STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DENTAL BOARD OF CALIFORNIA
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DENTAL BOARD OF CALIFORNIA

NOTICE OF TELECONFERENCE MEETING
March 14, 2022

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

Action may be taken on any item listed on the agenda.

The Dental Board of California (Board) will meet by teleconference at:

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

In accordance with Government Code section 11133 and Governor Gavin Newsom's Executive Order N-1-22, this meeting will be held by teleconference with no physical public location.

Important Notice to the Public: The Board will hold this meeting via WebEx Events. Instructions to connect to the meeting can be found HERE.

To participate in the WebEx Events meeting on **Monday, March 14, 2022**, please log on to this website the day of the meeting:

https://dca-meetings.webex.com/dca-meetings/j.php?MTID=m29b446a79864334ea44e05fe94a0bf20

Event number: 2497 908 6849
Event password: DBC03142022 (32203142 from phones)

Due to potential technical difficulties, please consider submitting written comments by March 11, 2022, to dentalboard@dca.ca.gov for consideration.

AGENDA

1. Call to Order/Roll Call/Establishment of a Quorum

2. Public Comment on Items Not on the Agenda
   Note: The Board may not discuss or take action on any matter raised during this Public Comment section, except to decide whether to place the matter on the agenda of a future meeting. (Government Code sections 11125 and 11125.7(a).)

3. Discussion and Possible Action on February 10-11, 2022 Board Meeting Minutes

4. Discussion and Possible Action to Consider Comments Received During the 45-Day Comment Period and Proposed Responses Thereto for the Board's Rulemaking to Amend California Code of Regulations, Title 16, Sections 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1044, 1044.1, 1044.2, 1044.3, and 1044.5, 1070.8, Adopt Sections 1017.1, 1043.8.1, and 1043.9, 1043.9.1, 1043.9.2, and Repeal Section 1044.4 Relating to the SB 501 (Anesthesia and Sedation) Rulemaking

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

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

7. Adjournment

This agenda can be found on the Dental Board of California website at dbc.ca.gov. The time and order of agenda items are subject to change at the discretion of the Board President and may be taken out of order. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board are open to the public.

The meeting will be webcast, provided there are no unforeseen technical difficulties or limitations. To view the webcast, please visit thedcapage.wordpress.com/webcasts/. The meeting will not be cancelled if webcast is not available. Meeting adjournment may not be webcast if it is the only item that occurs after a closed session.

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the Board prior to the Board taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before the Board, but the Board President may,

at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before the Board to discuss items not on the agenda; however, the Board can neither discuss nor take official action on these items at the time of the same meeting (Government Code sections 11125, 11125.7(a)).

This meeting is being held via WebEx Events. The meeting is accessible to the physically disabled. A person who needs disability-related accommodations or modifications to participate in the meeting may make a request by contacting Sarah Wallace, Interim Executive Officer, at Dental Board of California, 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, or by phone at (916) 263-2300. Providing your request at least five (5) business days prior to the meeting will help ensure availability of the requested accommodations. TDD Line: (877) 729-7789

DENTAL BOARD OF CALIFORNIA
MEETING MINUTES
February 10-11, 2022

NOTE: In accordance with Government Code Section 11133 and Governor Gavin Newsom's Executive Order N-1-22, the Dental Board of California (Board) met on February 10-11, 2022, via teleconference/WebEx Events, and no public locations or teleconference locations were provided.

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

Members Absent:
None

Staff Present:
Sarah Wallace, Interim Executive Officer
Carlos Alvarez, Chief of Enforcement Field Offices
Bernal Vaba, Chief of Regulatory Compliance and Discipline
Tina Vallery, Chief of Administration and Licensing
Jessica Olney, Anesthesia Unit Manager
Paige Ragali, Acting Dentistry Licensing and Examination Unit Manager
Emilia Zuloaga, Complaint and Compliance Unit Manager
Mirela Taran, Administrative Analyst
David Bruggeman, Legislative and Regulatory Specialist
Kristy Schieldge, Regulatory Counsel, Attorney IV, Department of Consumer Affairs (DCA)
Tara Welch, Board Counsel, Attorney III, DCA

9:00 a.m., Thursday, February 10, 2022

Agenda Item 1: Call to Order/Roll Call/Establishment of a Quorum
The Board President, Dr. Alan Felsenfeld, called the meeting to order at 9:06 a.m. The Board Secretary, Dr. Sonia Molina, called the roll; 12 Board Members were present, and a quorum was established.

Agenda Item 2: Public Comment on Items Not on the Agenda
There were no public comments made on items not on the agenda.

Agenda Item 3: Discussion and Possible Action on November 18-19, 2021 Board Meeting Minutes
Board Member, Ms. Joanne Pacheco, requested an amendment to the meeting minutes on page 3, Agenda Item 5, fifth paragraph, first line, to strike and replace "Dr. Rosalinda Olague" with "Ms. Rosalinda Olague." In addition, Ms. Pacheco requested amendments on page 18, Agenda Item 26(b), first paragraph, first line, to strike and replace "Heider" with "Heidi," and on page 20, eleventh paragraph, sixth and ninth line, to strike and replace "Mr. Waldschmidt" with "Dr. Waldschmidt."

Motion/Second/Call (M/S/C) (Medina/Yu) to approve the November 18-19, 2021 meeting minutes as revised.

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

The motion passed. There were no public comments made on this item.

Agenda Item 4: Board President Report
President Felsenfeld reported that attended the January 22, 2022 Dental Hygiene Board of California (DHBC), January 28, 2022 Dental Assisting Council (DAC), and the January 25, 2022 DCA Leadership (alongside Board Member Dr. James Yu) meetings. President Felsenfeld mentioned that he and Dr. Yu will be attending the annual Board President's Training hosted by DCA in the following week. He noted that he continues to meet with the Board's Interim Executive Officer on a weekly basis to discuss issues before the Board. He indicated that he is becoming well-oriented on the day-to-day processes of the Board as well as its interactions with outside organizations. He deeply regrets that the Board is unable to meet in-person during the February meeting but nonetheless looks forward to meeting in-person in the near future.

There were no public comments made on this item.

Agenda Item 5: Interim Executive Officer Report

Ms. Sarah Wallace, Interim Executive Officer, provided a report on the Board's personnel updates, DCA Director waiver orders, Governor executive orders, Board Strategic Plan, COVID-19 vaccination and testing requirements, and Executive Officer salary level increase. On December 30, 2021, Karen Fischer, the Board's Executive Officer, officially retired, and on December 31, 2021, Ms. Wallace began her responsibilities. Ms. Wallace noted that on January 31, 2022, Assembly Bill (AB) 1733 (Quirk, 2022) was introduced and would amend the Bagley-Keene Open Meeting Act. Ms. Wallace noted that the bill appeared to be a resurrected version of AB 885 (Quirk, 2021) and would allow the Board to continue to meet via teleconference.

Board Member, Dr. Steven Morrow, inquired whether the Board's staff vacancy rate is normal or if it is an excessive vacancy number, and if it is unusual, whether Ms. Wallace had any ideas or concerns regarding what had brought about this number of vacancies. Ms. Wallace responded that it is a high vacancy rate; the Board has had difficulty finding qualified candidates for several vacant positions. Ms. Wallace has had discussions with the DCA Budget Office about these issues, and high staff vacancies seem to be a statewide theme and not necessarily unique to the Board. Currently, the Board is working with the Office of Human Resources (OHR) to improve recruitment strategies and advertisements.

The Board received public comment. Mr. Michael Commanatore asked how the complaint department handles complaints and whether there has been any improvement in the last ten years.

Agenda Item 6: Report on Department of Consumer Affairs (DCA) Activities

Ms. Brianna Miller, DCA Board and Bureau Relations Manager, provided a departmental update. She expressed appreciation for all Board Members and staff who continue to serve through a pandemic that has affected everyone in many ways. California and DCA have continued to adhere to health and safety mandates to protect employees, consumers, and communities from the spread of COVID-19. State workers must show proof of COVID-19 vaccination or be subject to regular testing when working or meeting onsite. Ms. Miller indicated that the new state public health order, which will lift the universal masking for vaccinated individuals, will take effect on February 16, 2022. Furthermore, boards are urged to prepare for the possibility of in-person meetings after March 31, 2022. Before attending any in-person meeting, Board Members must verify full vaccination with DCA's OHR or participate in COVID-19 testing. Ms. Miller addressed board appointments and recruitment, the Enlightened Licensing Project, and required Board Member trainings.

The Board received public comment. Mr. Michael Commanatore requested a future agenda topic on transparency of the Compliant and Compliance Unit within the Board.

Agenda Item 7: Budget Report

Mr. Bill Loyd, DCA Budget Analyst, provided a report on the State Dentistry Fund, which the Board manages, for fiscal year (FY) 2021-22. He stated that on January 10, 2022, the Governor's Budget was released and provided updated budget numbers for the Board to include incremental adjustments to the Board's current year 2021-22 and the budget year 2022-23. In 2021-22 and based on the Governor's Budget, the Board projects an estimated $18.5 million in revenue. This number is estimated to remain fairly stable; however, the DCA Budget Office will continue to monitor revenue and report back to the Board if any significant variances are detected. The Board's expenditures for the current year are budgeted at $18.8 million; however, as of fiscal month five, it is projected that the Board will spend approximately $16.2 million.

There were no public comments made on this item.

Agenda Item 8: Report on the January 28, 2022 Meeting of the Dental Assisting Council (DAC)

Ms. Jeri Fowler, Chair of the DAC, provided a verbal report on the January 28, 2022 DAC meeting.

Dr. Morrow asked if the two-member working group has considered presenting survey questions to patients regarding quality of care. Ms. Fowler replied that currently there are no questions on the survey that are addressed to patients. Board Member, Dr. Alicia Montell, asked for clarification on how registered dental assistants in extended functions (RDAEFs) having the ability to administer anesthesia will elevate a patient's experience. Ms. Fowler replied that in many instances during a procedure, the RDAEF is left alone to complete a procedure. In the course of the work that the RDAEF is conducting, frequently, anesthesia is depleted and needs reinforcing. As a result, the RDAEF must ask the doctor to administer additional anesthesia. There is a period of time that the patient is waiting for additional anesthesia and once that comes, anesthesia needs to become effective before the RDAEF can resume their work. This process overall lengthens the procedure time.

The Board received public comment. Ms. Susan McLearan, California Dental Hygienists' Association (CDHA), stated that CDHA applauded the efforts of the two-member working group to develop meaningful data on the need for RDAEFs to be trained to administer local anesthesia and nitrous oxide. However, CDHA stands firmly opposed to that concept based on the facts that implementation would result in the reduction of educational standards and potential harm to consumers. Furthermore, the data presented so far does not support the need for this expansion of scope of practice. Ms. McLearan referred the Board to the CDHA objections raised during the Board's November 29, 2018 meeting and the CDHA letter with attachments and other objections submitted for that meeting.

Agenda Item 9: Discussion and Possible Action Regarding Appointment of DAC Members

Board Member, Ms. Rosalinda Olague, thanked Board staff and all 37 registered dental assistants (RDAs) who showed interest and completed the application to become a

DAC member. The Board Subcommittee, Ms. Olague and Ms. Pacheco (Subcommittee), selected candidates from the 37 applications and conducted 16 interviews. The Subcommittee recommended De'Andra Epps-Robbins, RDA, and Kandice Rae Pliss, RDA, to be appointed to fill the two open positions for Clinical Members on the DAC. The Subcommittee also recommended the Board reappoint Cara Miyasaki, RDA, RDHEF, MS, to fill the vacancy of the DAC member who is employed as a faculty member of an RDA educational program. Ms. Miyasaki has served a partial term, which expires in March 2022 and, if reappointed to the same position for a term of four years, Ms. Miyasaki's new term would expire in March 2026.

(M/S/C) (McKenzie/Morrow) to accept the Subcommittee's recommendation to appoint De'Andra Epps-Robbins, RDA, to the DAC.

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

The motion passed. There were no public comments made on this item.

(M/S/C) (McKenzie/Morrow) to accept the Subcommittee's recommendation to appoint Kandice Rae Pliss, RDA, to the DAC.

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

The motion passed. There were no public comments made on this item.

(M/S/C) (Larin/Chan) to accept the Subcommittee's recommendation to reappoint Cara Miyasaki, RDA, RDHEF, MS, as the DAC member employed as a faculty member of an RDA educational program approved by the Board.

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

The motion passed. There were no public comments made on this item.

Agenda Item 10: Enforcement
Agenda Item 10(a): Update on "Attorney General's Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies, Business and Professions Code Section 312.2, January 1, 2022"
Carl Sonne, Senior Assistant Deputy Attorney General, Office of the Attorney General, provided a verbal update and presentation on the Attorney General's Annual Report.

There were no public comments made on this item.

At 10:40 a.m., the Board recessed for a break.

At 10:55 a.m., the Board reconvened.

Agenda Item 10(b): Review of Statistics and Trends
Carlos Alvarez, Chief of Enforcement Field Offices, provided the report, which is available in the meeting materials.

Board Member, Dr. Chan, asked if there have been any trends or upticks with post-COVID 2020-2021 regarding complaints on the hygiene of dental offices. Mr. Alvarez responded that the Board has not received any complaints for unsanitary conditions regarding COVID-19. If the Board did receive complaints related to COVID-19, they would be forwarded to county and state health facilities.

The Board received public comment. Dr. Bruce Whitcher applauded Ms. Wallace for pointing out that there is a reason for the uptick in accusations that went up to 96, which is an increase over last year. Dr. Whitcher reiterated that things seem to be headed in the right direction.

Agenda Item 11: Examinations
Agenda Item 11(a): Report from Commission on Dental Competency Assessment and Western Regional Examining Board (CDCA-WREB)
Dr. William Pappas, President of ADEX, provided a verbal report on their activities. Dr. Pappas noted that while he does not have a formal report, he welcomes any questions and future topics Board Members have.

There were no public comments made on this item.

Agenda Item 11(b): Presentation on Central Regional Dental Testing Service Examination – *Central Regional Dental Testing Service, Inc. (CRDTS)*
Ms. Richael Cobler, Executive Director of CRDTS, provided a presentation to the Board regarding the CRDTS dental examination. Ms. Cobler expressed that CRDTS and the Board have the same mission of protecting the public. She elaborated that portability is a prominent discussion in the dental and dental hygiene testing world. Recently, states

such as Hawaii, have introduced legislation to revise their statutes and accept other nationally recognized clinical dental examinations. Ms. Cobler noted that CRDTS partners and works with Alpine Testing Solutions as their independent psychometric and testing data analysis.

Ms. Wallace noted that CRDTS reached out to Ms. Fischer and herself the previous year and had requested to provide a presentation to the Board regarding the CRDTS dental examination for licensure in California. Ms. Wallace added that the Board will have a discussion at a future meeting to determine whether or not Board Members want to embark on reviewing the CRDTS examination. She mentioned that she will work with President Felsenfeld on future agenda items and will invite the DCA Office of Professional Examination Services (OPES) to come back and present on the information that they have provided previously. At that meeting, depending on what the Board wishes to do, the Board would be asked to prioritize the review of the examinations so that it is clear which exam review should be conducted first.

There were no public comments made on this item.

Agenda Item 12: Licensing, Certifications, and Permits
Agenda Item 12(a): Review of Dental Licensure and Permit Statistics
Paige Ragali, Acting Licensing and Examination Unit Manager, provided the report, which is available in the meeting materials.

There were no public comments made on this item.

Agenda Item 12(b): General Anesthesia and Conscious Sedation Permit Evaluations Statistics
Jessica Olney, Anesthesia Unit Manager, provided the report, which is available in the meeting materials.

There were no public comments made on this item.

Agenda Item 13: Update on Pending Regulatory Packages
Ms. Wallace provided the report, which is available in the meeting materials. Ms. Wallace reported that the Board has been assigned new Regulatory Counsel, Ms. Kristy Schieldge, and hired a new Legislative and Regulatory specialist, Mr. David Bruggeman. Ms. Wallace was happy to report that the Diversion Evaluation Committee Membership rulemaking became effective on October 1, 2021.

The Senate Bill (SB) 501 Anesthesia and Sedation Requirements rulemaking was approved by the Board at the November 2021 Board Meeting. The package was submitted to the Office of Administrative Law (OAL) for publication, and the 45-day public comment period began on December 31, 2021 and will end on February 15, 2022. The Board has received a request for a public hearing, and staff have scheduled a public hearing via WebEx to be held on February 16, 2022. Ms. Wallace added that

the Board has scheduled a Board meeting on March 14, 2022, to consider comments received during the public comment period for the SB 501 rulemaking. The Board does expect that the rulemaking will require modified text.

The Board received public comment. Ms. Paula Lee, RDHAP, MPH, asked for an explanation on the mobile and portable dental unit registration requirements. Ms. Wallace responded that she would be happy to provide more information on this inquiry and instructed Ms. Lee to reach out to her.

Agenda Item 14: Discussion and Possible Action to Consider:
a. Comments Received During the 45-Day Public Comment Period Relative to Amendments to CCR, Title 16, Sections 1016 and 1017, and Adoption of CCR, Title 16, Section 1016.2 for Continuing Education
b. Adoption of Amendments CCR, Title 16, Sections 1016 and 1017, and Adoption of CCR, Title 16, Section 1016.2 for Continuing Education
Ms. Olney provided the report, which is available in the meeting materials. The initial rulemaking documents were submitted to OAL for publication on November 12, 2021, which initiated a 45-day comment period on the proposed regulation. Board staff received two comments related to the rulemaking.

(M/S/C) (Chan/Morrow) to approve the proposed amended regulatory text for sections 1016, 1016.2, and 1017, approve the responses drafted to address public comments received during the 45-day comment period on the Board's proposed regulation amending required continuing education, and direct staff to take all steps necessary to complete the rulemaking process, including sending out the modified text with these changes for an additional 15-day comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulation, and adopt the proposed regulations as described in the modified text notice for Title 16 CCR sections 1016, 1016.2, and 1017.

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

The motion passed. There were no public comments made on this item.

Agenda Item 15: Discussion and Consideration of Proposed Regulation to Amend CCR, Title 16, Section 1031 Related to the California Dentistry Law and Ethics Examination
Ms. Wallace provided the report, which is available in the meeting materials.

(M/S/C) (Chan/Pacheco) to approve the proposed amended regulatory text for section 1031 and direct staff to take all steps necessary to complete the rulemaking process, including sending out the modified text with these changes for an additional 15-day comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulation, and adopt the proposed regulations as described in the modified text notice for Title 16 CCR section 1031.

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

The motion passed. There were no public comments made on this item.

Agenda Item 16: Recess Open Session
President Felsenfeld recessed Open Session at 11:46 a.m.

*Agenda Item 17: Convene Closed Session
Closed Session was not convened as there were no items to discuss in closed session.

*Agenda Item 18: Pursuant to Government Code Section 1126(c)(3), the Board Will Meet in Closed Session to Deliberate and Vote on Disciplinary Matters, Including Stipulations and Proposed Decisions

*Agenda Item 19: Pursuant to Government Code Section 11126(c)(2), the Board Will Meet in Closed Session to Deliberate and Vote on Application(s) for Issuance of New License(s) to Replace Cancelled License(s)

*Agenda Item 20: Pursuant to Government Code Section 11126(a)(1), the Board will meet in Closed Session to Conduct Interviews, Discuss, and May Take Action on Possible Appointment of Executive Officer

*Agenda Item 21: Adjourn Closed Session

9:00 a.m., Friday, February 11, 2022

Agenda Item 22: Reconvene Open Session– Call to Order/Roll Call/Establishment of a Quorum
President Felsenfeld called the meeting to order at 9:05 a.m. Secretary Molina called the roll; 12 Board Members were present, and a quorum was established.

Agenda Item 23: President's Report on Closed Session Items
President Felsenfeld mentioned that no report would be provided as this agenda item was moot.

The Board did not take public comment on this item.

Agenda Item 24: Discussion and Possible Action Regarding Approval of California Northstate University (CNU), College of Dental Medicine
Ms. Wallace introduced the report, which is available in the meeting materials.

Kevin M. Keating, DDS, MS, Dean and a Professor at California Northstate University, provided a verbal report. He stated that CNU's College of Dental Medicine (CDM) is in operation and started orientation as of January 4, 2022. The first class is 38 out of 40 students who matriculated into the CDM and have met the national average for candidates accepted into dental schools around the country. The cohort that has currently matriculated will graduate in a three-and-a-half-year, Commission on Dental Accreditation (CODA) accredited, one-time delivery of the four-year curriculum and will graduate in July of 2025. In July of 2022, it is anticipated that the school will be starting its second cohort, which will graduate in 2026.

Dr. Chan asked for clarification on the meaning of programmatic accreditation by CODA. Dr. Pinelopi Xenoudi responded that in regard to programmatic accreditation, it refers to the process that is designed to ensure that the academic program has undergone a rigorous review process. In other words, the standards associated with a specific discipline. Additionally, the programmatic accreditation applies to one degree program, which is how CODA defines the accreditation sequence process. Dr. Keating added that programmatic accreditation would be for the Doctor of Dental Medicine (DMD) program and does not apply to residencies or other programs that might be added later on.

Dr. Morrow congratulated Dr. Keating and his colleagues at CNU in accomplishing the monumental task of giving birth to a CODA-approved dental education program. He asked when the students will achieve their clinical competencies and whether there are plans for students that rotate through Federally Qualified Health Centers (FQHCs) type clinics for part of their clinical education. Dr. Keating responded that CDM plans to have its future facility in the city of Elk Grove. The school is currently developing property options in and around Arco Arena and have many plans in place with many different challenges of starting a new school. The school plans in the curriculum up to eight weeks of rotation in the fourth year (D4). The school has FQHCs and Memorandum of Agreements (MOUs) which are being further developed.

Dr. Morrow asked how CNU's pre-dental education program and the DMD program operate and work together. Dr. Keating responded that it is a pathway program; the undergraduate campus is a health science campus. It is the vision that as the undergraduate campus grows, it will start adding other colleges to its curriculum.

Presently, CNU is a health science focused university. Dr. Morrow asked what the advantage is, from a standpoint of being accepted to the DMD program, if a student goes through the pre-dental program. Dr. Keating replied that the advantage is that the student is certain to receive an interview but is not guaranteed admission into the program; students still need to be academically competent.

Ms. Pacheco congratulated Dr. Keating and inquired whether CNU will have an interdisciplinary collaboration with dental hygiene programs. Dr. Keating replied that CNU has reached out and had communication with Sacramento City College and Carrington College hygiene program. However, this is a vision more than a reality presently. Dr. Xenoudi added that in regard to CDM's collaboration with the undergraduate college, College of Health Sciences (CHS), it would act as mentors for the pre-dental group. Dr. Morrow thanked Dr. Xenoudi for the clarification.

(M/S/C) (Chan/Pacheco) to grant provisional approval of the California Northstate University, College of Dental Medicine.

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

The motion passed. There were no public comments made on this item.

Agenda Item 25: Substance Use Awareness
Agenda Item 25(a): Presentation regarding Board's Diversion Program
Ms. Wallace introduced the Board's Diversion program. The program, established in statute, is intended to rehabilitate licensees whose competency may be impaired due to abuse of dangerous drugs or alcohol. The intent of the program is to treat afflicted licensees and return them to the practice of dentistry in a manner that will not endanger the public health and safety of Californians.

Ms. Virginia Matthews, Maximus representative, provided a verbal report of the Board's Diversion Program. Dr. Curtis Vixie, Co-Chair of the Diversion Evaluation Committee (DEC), shared his recovery story using the format that the program does when they have a sobriety meeting.

Board Member, Ms. Angelita Medina, thanked Dr. Vixie for sharing his powerful story and reiterated that she supports the Board's Diversion program. Dr. Montell verbalized her appreciation to Dr. Vixie and asked for a general time frame on how long participants take to return to work. Ms. Matthews replied that every case is handled individually, and they look at a number of things in order to determine whether the

participant is ready to return to work safely. Dr. Vixie added that they have the help of the treatment team to assist them in determining that time frame.

Dr. Montell inquired whether there is available data on people who have successfully finished the program but soon after relapsed. Ms. Matthews replied that they do not have that data specifically for the Board. However, the number is not tremendously high. She pointed out that she can send information to the Board regarding this question. Dr. Vixie roughly estimated that less than seven percent relapse after five years. Ms. Matthews replied that a study by authors McLellan and Skipper is a resource where one could locate that information. Dr. Morrow expressed his gratitude to Dr. Vixie for sharing his life story with the members of the Board and thanked him for his contribution to the profession.

There were no public comments made on this item.

At 10:47 a.m., the Board recessed for a break.

At 11:05 a.m., the Board reconvened.

Agenda Item 25(b): Diversion Program Report and Statistics
Mr. Bernal Vaba, Chief of Regulatory Compliance and Discipline, provided the report, which is available in the meeting materials. Mr. Vaba mentioned that the next DEC Meeting is scheduled for April 6, 2022.

There were no public comments made on this item.

Agenda Item 25(c): Controlled Substance Utilization Review and Evaluation System (CURES) Report
Mr. Alvarez provided the report, which is available in the meeting materials.

Dr. Morrow pointed out that the Board has 31,155 active licensed dentists as of December 31, 2021. However, as of December 2021, the number of registered DDS (Doctor of Dental Surgery)/DMD CURES users was 16,734. Dr. Morrow inquired if there is a particular reason as to why close to 50 percent of dentists are not registered with CURES. Mr. Alvarez replied that the Board attempts to obtain information when investigations are conducted from the Drug Enforcement Administration (DEA) office; however, the office does not release that information. He added that some licensees are not signed up with CURES as they do not write prescriptions. Dr. Morrow inquired whether the Board has any data on how many of those, out of the 31,155 dentists, have a license in California but are actively practicing in another state. Mr. Alvarez replied that he believes that information is present in reports but that the Board has not looked into licensees who are not signed up for CURES. Part of the Board's investigation once a complaint is received is that it can ask if the dentist is registered with CURES.

Dr. Morrow asked whether the Board has a responsibility regarding compliance with this statute and legal requirement by a dentist who is licensed, but not practicing, in California but actively practicing in another state. Mr. Alvarez replied that if the dentist is prescribing any prescriptions and is out of state, they still must comply with CURES. Dr. Morrow asked if the Board has a way of monitoring out of compliance. Mr. Alvarez responded that would come from the Board of Pharmacy or a pharmacist who will report it to the Board. Dr. Morrow inquired whether the Board only has responsibility for those dentists who write prescriptions that are filled in California or whether the Board has responsibility for a dentist who has a license in multiple states, including California, but issues prescriptions in another state. Mr. Alvarez replied that if they are licensed with the State of California but are out-of-state and filling prescriptions in-state, they are still obligated to comply with the laws.

There were no public comments made on this item.

Agenda Item 25(d): Update on New Electronic Prescribing Laws

Mr. Alvarez provided the report, which is available in the meeting materials. Mr. Alvarez reported that the Dental Board has had a few inquiries relating to the new prescribing laws. The Board has had one referral coming in from a pharmacy who reported that a licensee was not in compliance. As the reason for non-compliance was due to technological failure, it was classified as an exemption based on the new electronic prescribing laws.

There were no public comments made on this item.

Agenda Item 26(a): Update Regarding Board Implementation of SB 501 (Glazer, Chapter 929, Statutes of 2018)

Ms. Olney provided the report, which is available in the meeting materials. Ms. Olney commented that Board staff have received a request to hold a public hearing on the proposed language, which will be scheduled for February 16, 2022. The meeting will be held via WebEx and will be facilitated by Board staff. This hearing will be an opportunity for the public to submit verbal comments on the proposed language. In addition, a Board meeting has been scheduled for March 14, 2022, to address public comments received and approve any modifications to the proposed language.

President Felsenfeld pointed out that 23 percent of permit holders did not take advantage of the extended renewal period and inquired if there are particular reasons as to why permittees chose not to renew. Ms. Olney replied that when staff made phone calls, they received a variety of responses from permittees for non-renewal. Board staff contacted permit holders by mail, telephone, and email. In addition to live phone calls initiated by staff, there were also automated phone calls with a pre-recorded message that went out to all permittees.

The Board received public comment. Dr. Bruce Whitcher, representing himself and the California Dental Association (CDA), stated that there was a lot of difficulty with the

department finding a vendor for the original Breeze system. When the Breeze system completed their contract, they left it to the boards and bureaus to outsource any further Information Technology (IT) that would be needed. Dr. Whitcher noted that he hopes that the Board does not run into the same problem with the Office of Information Services (OIS) finding a contractor to continue with the Breeze operations and make necessary changes. Dr. Whitcher also believes SB 652 will extend the implementation date out until 2023.

Ms. Monica Miller, CANA representative, reiterated that they will be attending and providing comments both written and verbally at the Board's February 16, 2022 hearing, as they have concerns regarding these regulations.

Agenda Item 26(b): Discussion and Possible Action on Supplemental Report to the California State Legislature Regarding Findings Relevant to Inform Dental Anesthesia and Sedation Standards as Required by SB 501 (Glazer, Chapter 929, Statutes of 2018) and Business and Professions Code Section 1601.4, subdivision (a)(2)
Ms. Olney provided the report, which is available in the meeting materials.

Dr. Chan inquired about provider specificity data, the curriculum for pediatric dentist postgraduate training in regard to anesthesia, and whether periodontists and endodontists can do sufficient anesthesia, general anesthesia, or sedation in their types of practices where that type of identifier might be needed. Dr. Chan stated the Board needs to identify gaps that would lead to deaths or hospitalizations in order to improve the process. Ms. Olney clarified that a general dentist cannot provide deep sedation or general anesthesia; only a dentist who has completed a residency in either oral and maxillofacial facial surgery or anesthesia can qualify for that permit. Regarding the question on "other" on the provider categories, the statute does not specify what constitutes other categories.

President Felsenfeld asked whether permittees would have to have training, which the Board defined in statute, before they are able to obtain a particular permit. Ms. Olney replied that each permit has its own residency or course requirement to qualify for the permit.

The Board received public comment. Dr. Whitcher thanked the Board for the presentation that was provided and for addressing comments that came in from other members of the public.

Agenda Item 27: Presentation and Possible Discussion on Permitting of Certified Registered Nurse Anesthetists to Administer General Anesthesia in Dental Health Care Settings – *California Association of Nurse Anesthetists (CANA)*
Ms. Melanie Rowe, CRNA, CANA representative, provided a presentation on the permitting of Certified Registered Nurse Anesthetists (CRNAs) to administer general anesthesia in dental healthcare settings, which is available in the meeting materials.

The Board received public comment. Due to technical difficulties experienced by Dr. Whitcher during the meeting, he submitted written public comments on this item to the Board on February 15, 2022.

Agenda Item 28: Report on January 12, 2022 Meeting of the Elective Facial Cosmetic Surgery Permit Credentialing Committee (Committee) and Discussion and Possible Action to Accept Committee Recommendations for Issuance of Permits
Ms. Ragali provided the report, which is available in the meeting materials. A brief background on the Elective Facial Cosmetic Surgery Permit and Committee was provided.

(M/S/C) (Larin/Morrow) to accept the EFCS Credentialing Committee Report and issue to Ian Lehrer, DDS, an EFCS Permit for unlimited Category II privileges.

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

The motion passed.

The Board received public comment. Dr. Whitcher stated he had technical difficulties providing public comment for Agenda Item 27 and agreed to submit written comments in writing for that agenda item.

Agenda Item 29: Legislation – Update, Discussion, and Possible Action on:
Agenda Item 29(a): 2022 Tentative Legislative Calendar – Information Only
Mr. Bruggeman provided an overview of the 2022 Tentative Legislative Calendar, which is available in the meeting materials. Mr. Bruggeman highlighted three particularly important dates as the Board moves forward in terms of how the legislation will proceed this year. He noted that the last day for bills to be introduced this year is February 18, 2022; the last day for bills to be passed out of the house of origin is March 27, 2022; and the last day that each house has to pass bills for this year is August 31, 2022.

There were no public comments made on this item.

Agenda Item 29(b) –(s): Update, Discussion, and Possible Action on Legislation
Mr. Bruggeman provided the report, which is available in the meeting materials. Board staff identified seven bills, Assembly Bill (AB) 225, AB 562, AB 646, AB 657, AB 1102, Senate Bill (SB) 49, and SB 731 of potential interest to the Board and two bills, SB 652 and SB 889, of having a direct impact on the Board. Mr. Bruggeman noted that nine bills, AB 2, AB 29, AB 54, AB 885, AB 1026, AB 1236, AB 1386, AB 1498, and SB 772, have been tracked by the Board but have died in the Legislature.

SB 652

The Board anticipates this bill to be the legislative vehicle for the Board's legislative proposal. As it is currently written, it would extend the current requirements for dental patients under 13 years of age specifically that an operating dentist and at least two additional personnel be present through a procedure involving deep sedation or general anesthesia and that the dentist and one additional personnel maintain current certification in advanced cardiac life support to all patients regardless of age. The Board anticipates amendments to this bill, but they have not yet been added to the bill.

(M/S/C) (Chan/McKenzie) to support SB 652 pending the amendments publication.

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

The motion passed.

The Board received public comment. Dr. Whitcher, representing CDA, would support a legislative extension of SB 501and believes CDA is heavily involved in the development of the language to be added to this bill.

SB 889

SB 889 was introduced on January 31, 2021, and has been referred to the Senate Committee on Business, Professions, and Economic Development. Currently, there is no hearing date scheduled. This bill would amend provisions of the Business and Professions Code (BPC) concerning the use of deep sedation and general anesthesia involving nurse anesthetists. It would modify the requirement in BPC section 2827 that a dentist would have to have a sedation permit for a nurse anesthetist to administer general anesthetic. This bill would allow a nurse anesthetist to administer deep sedation or general anesthetic if it is done in compliance with article 2.75 of the Dental Practice Act (DPA). Language in the bill would allow a nurse anesthetist to administer deep sedation or a general anesthetic even though the dentist lacks the permit to do so. The Board will need additional time to do a more complete analysis of the impact of this legislation.

Dr. Chan noted that he is concerned about whether or not nurse anesthetists would perform these procedures at the direction of a dentist who does not have a general anesthesia permit.

(M/S/C) (Morrow/Chan) to take a watch position on SB 889.

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

The motion passed.

The Board received public comment. Dr. Whitcher, representing himself and CDA, supported a watch position on SB 889. He noted that there are outstanding, unresolved issues that need to be addressed in relation to this bill.

Ms. Miller noted that CANA will continue to work with Board staff and the authors of the SB 889 bill. She reiterated that the clear intent of this bill is to allow for nurse anesthetists to hold the dental anesthesia permit; therefore, allowing the dentist to not have to obtain that permit should the dentist decide that they want to provide a service of anesthesia particularly in areas that have a lack of providers and a high medical population.

Agenda Item 30: Discussion and Possible Action Regarding Legislative Proposal to Amend Business and Professions Code Sections 1750.2, 1750.4, and 1752.1 to Specify Time Limits for Acceptance of Course Certifications for Orthodontic Assistant (OA) Permit and Dental Sedation Assistant (DSA) Permit Applications and Clarify Board-Approved Course Requirements for Registered Dental Assistant (RDA) Applicants
Ms. Wallace provided the report, which is available in the meeting materials. She stated that the legislative proposal regarding specifying time limits for acceptance of course certifications came from a recommendation from the DAC. Board staff had previously identified inconsistency issues with statutory application requirements between RDAs, orthodontic assistants (OAs), and dental sedation assistants (DSAs).

(M/S/C) (Yu/Pacheco) to include in the Board's next Sunset Review Report a recommendation to amend BPC sections 1750.2, 1750.4, and 1752.1 to clarify the RDA, OA, and DSA course completion requirements for license and permit applications.

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

The motion passed.

The Board received public comment. Claudia Pohl stated that she is in support of these changes and appreciates staff's effort.

Agenda Item 31: Discussion on Prospective Legislative Proposals
Ms. Wallace provided the report, which is available in the meeting materials. There were no stakeholder proposals presented to the Board and no public comments made on this item.

Agenda Item 32: Adjournment
President Felsenfeld adjourned the meeting at 12:37 p.m.

**Agenda Items for this meeting were not discussed as there were no closed session items for discussion.*

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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MEMORANDUM

DATE	March 9, 2022
TO	Members of the Dental Board of California
FROM	David Bruggeman, Legislative and Regulatory Specialist Dental Board of California
SUBJECTS	**Agenda Item 4:** Discussion and Possible Action to Consider Comments Received During the 45-Day Comment Period and Proposed Responses Thereto for the Board's Rulemaking to Amend California Code of Regulations, Title 16, Sections 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1044, 1044.1, 1044.2, 1044.3, and 1044.5, 1070.8, Adopt Sections 1017.1, 1043.8.1, and 1043.9,1043.9.1, 1043.9.2, and Repeal Section 1044.4 Relating to the SB 501 (Anesthesia and Sedation) Rulemaking. **Agenda Item 5:** Discussion and Possible Action to Consider Adoption of Proposed Amendments to California Code of Regulations, Title 16, Sections 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1044, 1044.1, 1044.2, 1044.3, 1044.5, 1070.8, 1017.1, 1043.8.1, 1043.9, 1043.9.1, 1043.9.2, and 1044.4 Relating to the SB 501 (Anesthesia and Sedation) Rulemaking.

Background Information:

At the November 19, 2021, meeting the Board approved proposed language for the implementation of SB 501 (Glazer, Chapter 929, Statutes of 2018). The language Amends Title 16, California Code of Regulations (CCR) Sections 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1043.8.1, 1044, 1044.1, 1044.2, 1044.3, 1044.4, 1044.5, & 1070.8 Adopt Sections 1017.1, Adopts a new Article 5.1 and 16 CCR Sections 1043.9, 1043.9.1 and 1043.9.2 concerning regulations for the permitting, ordering and administering of sedation for dental purposes. The Board directed staff to take all steps necessary to initiate the formal rulemaking process, including noticing the proposed language for a 45-day public comment period, holding a public hearing if requested, and authorizing the Executive Officer to make any non-substantive changes to the rulemaking package.

During the 45-day public comment period, the Board received both written public comments on the proposed regulations as well as requests for a public hearing. The hearing was held on February 16, 2022, through Webex teleconferencing and seven witnesses offered public

comment. Staff has prepared the attached summary of the comments received in writing and at the hearing and included proposed responses for the Board to review and possibly approve. All written comments received as well as a transcript from the February 16, 2022 public hearing are also attached for your review.

Staff Recommendation for Agenda Item 4

The members should review the comments and staff's recommended responses provided in the meeting materials and consider whether to accept or reject any of these comments. After review, the Board may consider any of the following actions:

Option No. 1 (If the members agree with the staff recommended responses): Direct staff to proceed as recommended to accept or reject comments as specified and provide the responses to the comments as indicated in the meeting materials.

Option No. 2: (If the members have any edits to the recommended responses or disagree with staff and wish to accept any comments or make any other changes to its responses): Direct staff to accept the following comments and make the following edits to the text: [identify comments to accept or reject and text to change here], but otherwise proceed as recommended to accept or reject comments as specified and provide the responses to the comments as indicated in the meeting materials.

Agenda Item 5 Proposed Text Modifications:

Staff has identified suggested text changes in the proposed regulations that need to be made to ensure that the regulatory proposals fully implement the requirements of SB 501, clean-up typographical errors, and correct inadvertent omissions of necessary information in the proposal. Staff have also made recommended edits based on their recommendations to accept comments as discussed above in Agenda Item 4 and the staff's attached summary of comments document. These changes are in yellow highlight, in addition to double underline (for additions) and double strikethrough (for deletions). The changes are described below, and the full modified text of the proposed regulations is attached as well.

Modifications to Regulatory Text:

1. Make nonsubstantial clarifying changes to the introduction to the proposal including adding the word "and', adding titles for the existing chapter 4 and article title references to the introduction to the regulatory proposal so that the regulated community has notice of where section 1017.1 is located.

2. Strike the reference in the introduction to the proposed repeal of repeal section 1044.4 of Article 5.5 of Chapter 2, which, as discussed below, the Board proposes to retain.

3. As discussed below, proposed section 1043.8.1 would strike and renumber subsection (c). As a result, the existing cross-reference in this subsection needs to be renumbered to match 1043.8.1, as follows:

   (a) As a condition of renewal, each licensee who holds a general anesthesia

permit with a pediatric endorsement shall provide documentation to the Board showing completion of twenty (20) cases of general anesthesia to pediatric patients as providedin Section 1043.8.1, subsections (c)-(~~e~~d).

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

   (b) As a condition of renewal, each dentist licensee who holds a moderate sedation permit with a pediatric endorsement shall confirm to the Board in writing the following as part of the permit renewal requirements in Section 1043.8 ("application"):

   (1) Whether the licensee completed at least twenty (20) cases of moderate sedation for children under thirteen years of age in the 24-month time period immediately preceding application for their current permit renewal either independently and/or under the direct supervision of another permit holder;

   (2) Whether the licensee completed at least twenty (20) cases of moderate sedation for children under seven years of age in the 24-month time period immediately preceding application for their current permit renewal either independently and/or under the direct supervision of another permit holder, and;

   (3) If applicable, if the licensee lacks sufficient cases, whether the licensee is administering moderate sedation to patients under seven years of age only under the direct supervision of a permit holder who meets the qualifications of 1647.3 of the Code.

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

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

	$~~500~~524

(q) Application for General Aanesthesia (for dentist and physician licensees) or conscious Moderate Ssedation Ppermit	
(ag) Application for Pediatric Endorsement for General Anesthesia Permit (for dentist and physician licensees)	$532

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

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

   Section 1043.9(b): "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility ~~which~~ that is accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

   Section 1044(a): "Outpatient basis" means "outpatient setting" as used in Health and Safety Code Sections 1248 and 1248.1 and means all settings where oral conscious sedation is being provided to dental patients with the exception of a treatment facility ~~which~~ that is accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

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

   § 1043.3. Onsite Inspections.

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

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

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

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

   (~~b~~c) ~~An applicant who has failed the evaluation may appeal that decision to the board and request a reevaluation. This appeal must be made in writing to the board stating the grounds for the appeal within thirty (30) days after the date on which the evaluation results were mailed. However, p~~Pursuant to ~~s~~Sections 1646.4(a), 1646.9(d) and 1647.7(a) of the ~~c~~Code, the permit of any applicant who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the applicant of the failure unless, within that time period, the applicant has retaken and passed an onsite inspection and evaluation.
   ~~Upon receipt of the appeal request and an additional evaluation fee, the board will schedule an independent reevaluation of the appellant.~~ If an applicant has failed two evaluations, the board will decide the matter and may grant or deny a permit or request further evaluation of the appellant with a board member or other board appointed representative being present. The applicant must successfully complete remedial education in a subject within the scope of the onsite inspection and evaluation as determined by the Board prior to being ~~retested~~ reevaluated if a third onsite inspection and evaluation is granted or prior to the issuance of a new permit.

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

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

12. Amend introductory text of section 1043.9.2 to include equipment standards for maintenance, testing and inspection as well as the appropriate size of equipment, medication, and resuscitation capabilities for a pediatric population. This addition would

be consistent with the language on the PMSP-1 form and the language for equipment standards for other anesthesia and sedation types. The text would be modified to state:

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

13. Amend section 1043.9.2 to delete the requirement that equipment must be maintained in good operating condition. Because other proposed changes (explained in paragraph 12 above) would add the requirement that equipment be maintained, tested, and inspected according to manufacturers' specifications (i.e., "good operating condition" standards), the language in this section is not necessary. The text would be modified to state:

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

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

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

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

Modifications to Forms:

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

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

paid and your name appears on ~~either~~ the ~~BOE~~ State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

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

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

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

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

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

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

20. Amend the GAP-1 Form section at the end of the form that reproduces section 1043.8.1 for the convenience of the applicants and make corresponding changes to proposed section 1043.8.1 consistent with the amendments discussed above in paragraph 11.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

paid and your name appears on ~~either~~ the ~~BOE~~ State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

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

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

33. Amend the PMSP-1 Form in question 14 to replace the word “factility” with the word “facility.”

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

4. MINIMAL SEDATION TRAINING VERIFICATION:

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

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

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

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

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

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

may be suspended if you have a state tax obligation and the state tax obligation is not paid and your name appears on ~~either~~ the ~~BOE~~ State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

37. Amend the OCS-C Form to add a question 10 on how applicants are qualifying for the permit under Business and Professions Code section 1647.20 in response to comments submitted by the California Dental Association. This section describes four requirements for an applicant to demonstrate either education or experience that would satisfy the Board as to the applicant's qualifications to administer oral conscious sedation and are needed to implement the educational qualifications provisions of BPC section 1647.20. These questions are being moved from existing application OCS-3, which the Board previously adopted to implement these requirements (which remain unchanged from SB 501). Applicants can satisfy this section by meeting one of the four requirements, and would indicate which one they meet on Form OCS-C. In the Board's experience, these questions, and the applicable documentation requirements (including proof of academic completion via a diploma) provide the Board with sufficient verification of the educational experience requirements for this permit. Cross-references have been added to the existing text from Form OCS-3 to further clarify the Board's existing educational requirements and provide notice to the applicants of the educational criteria necessary to qualify for the permit. The text would be modified to state:

10. **QUALIFICATION** – INDICATE UNDER WHICH METHOD LISTED BELOW YOU QUALIFY FOR AN ORAL CONSCIOUS SEDATION CERTIFICATE FOR ADULTS AND ATTACH APPROPRIATE DOCUMENTATION AS SET FORTH BELOW.

☐ SUCCESSFUL COMPLETION OF A POSTGRADUATE PROGRAM IN ORAL AND MAXILLOFACIAL SURGERY APPROVED BY THE COMMISSION ON DENTAL ACCREDITATION OR A COMPARABLE ORGANIZATION APPROVED BY THE BOARD AS PROVIDED IN TITLE 16, CALIFORNIA CODE OF REGULATIONS (CCR) SECTION 1044.2. APPLICANT MUST PROVIDE A COPY OF HIS OR HER DIPLOMA.

☐ SUCCESSFUL COMPLETION OF A PERIODONTICS OR GENERAL PRACTICE RESIDENCY OR ADVANCED EDUCATION IN A GENERAL DENTISTRY POST-DOCTORAL PROGRAM ACCREDITED BY THE COMMISSION ON DENTAL ACCREDITATION THAT MEETS THE DIDACTIC AND CLINICAL REQUIREMENTS OF CCR SECTION 1044.3. APPLICANT MUST PROVIDE A COPY OF HIS OR HER DIPLOMA.

☐ SUCCESSFUL COMPLETION OF A BOARD-APPROVED EDUCATIONAL PROGRAM ON ORAL MEDICATIONS AND SEDATION MEETING THE REQUIREMENTS IN CCR SECTION 1044.3.

☐ DOCUMENTATION OF 10 SUCCESSFUL CASES OF ORAL CONSCIOUS SEDATION PERFORMED BY THE APPLICANT ON ADULT PATIENTS IN ANY THREE-YEAR PERIOD ENDING NO LATER THAN DECEMBER 31, 2005 AS PROVIDED IN BPC SECTION 1647.20(d)). ATTACH FORM OCS-4 WITH COPY OF TREATMENT RECORDS.

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

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

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

Board staff recommends these modifications be made to avoid confusion in the regulated community regarding the meaning and applicability of these provisions. Making these modifications will also facilitate the timely implementation of these regulations and avoid a gap in anesthesia and sedation permits.

In addition, to ensure that all rationales and documents relied upon in consideration of these proposed amendments are included as part of the rulemaking file, staff recommend adding the following to the rulemaking file, which must be noticed for public comment as part of any proposed modifications to text, as follows:

a. Form: "Application for Oral Conscious Sedation for Minors Certificate" OCS-1 (Rev. 01/05) [showing repealed]
b. Form: "Application for Adult Oral Conscious Sedation Certificate" OCS-3 (Rev. 03/07) [showing repealed]
c. Form OCS-4 (Rev 03/07) "Documentation of Oral Conscious Sedation Cases"
d. Addendum to the Initial Statement of Reasons
e. Stats.1979, c. 886, p. 3071-3073, § 1.
f. The Joint Commission 70-year Historical Timeline published by the Joint Commission at https://www.jointcommission.org/-/media/enterprise-imagery/70th-anniversary/tjc-70-year-timeline-81121.pdf

These documents are attached to the memorandum for the Board's review and approval.

Staff Recommendation for Agenda Item 5:

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

Proposed Motion Language:

Option No. 1 (agree with staff recommendation): Approve the proposed modified text and documents added to the rulemaking file and direct staff to take all steps necessary to complete the rulemaking process, including sending out the modified text with these changes and notice of the addition of documents added to the rulemaking file for an additional 15-day comment period. If after the 15-day public comment period, no adverse

comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulation, and adopt the proposed regulations (including the decision not to repeal section 1044.4) as described in the modified text notice for 16 CCR sections 1017.1, 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1043.8.1, 1044, 1044.1, 1044.2, 1044.3, 1044.4, 1044.5,1070.8, 1043.9, 1043.9.1 and 1043.9.2.

Option No. 2 (wish to make modified text changes other than what is proposed): Approve the proposed modified text with the changes discussed at this meeting, which include [insert description of proposed change by section number or form here] and documents added to the rulemaking file and direct staff to take all steps necessary to complete the rulemaking process, including sending out the modified text with these changes and notice of the addition of documents added to the rulemaking file for an additional 15-day comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations, and adopt the proposed regulations (including the decision not to repeal section 1044.4) as described in the modified text notice and authorized at this meeting for 16 CCR sections 1017.1, 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1043.8.1, 1044, 1044.1, 1044.2, 1044.3, 1044.4, 1044.5,1070.8, 1043.9, 1043.9.1 and 1043.9.2.

Pros: Board approval of the proposed responses to comments and modified text will allow the rulemaking process to proceed. It will allow the proposed rules to be implemented without a gap in the anesthesia and sedation permitting process.

Cons: If the proposed response to comments and modified text are not approved, the rulemaking process cannot proceed. Without regulations in place, anesthesia and sedation permits cannot be applied for and/or granted in a manner consistent with SB 501 and the Dental Practice Act.

Documents included for reference:

1. Summary of Comments Received and Staff Recommendations for Responses to Comments on Proposed Amendments
2. Final Statement of Reasons, Minutes from May 31, 2006 Public Hearing, and letter from the California Dental Association dated May 24, 2006 in connection with regulatory changes to 16 CCR 1044
3. Written Comments Received During the Public Comment Period on Originally Proposed Regulatory Language
4. Transcript of February 16, 2022 regulations hearing
5. Proposed Modified Text
6. Proposed Documents Added to the Rulemaking File:
    g. Form: “Application for Oral Conscious Sedation for Minors Certificate” OCS-1 (Rev. 01/05) [showing repealed]
    h. Form: “Application for Adult Oral Conscious Sedation Certificate” OCS-3 (Rev. 03/07) [showing repealed]
    i. Form OCS-4 (Rev 03/07) “Documentation of Oral Conscious Sedation Cases”
    j. Addendum to the Initial Statement of Reasons

k. Stats.1979, c. 886, p. 3071-3073, § 1.
l. The Joint Commission 70-year Historical Timeline published by the Joint Commission at https://www.jointcommission.org/-/media/enterprise-imagery/70th-anniversary/tjc-70-year-timeline-81121.pdf

Summary of Comments Received and Staff Recommendations for Responses to Comments on Proposed Rulemaking to Amend Section 1021 of Article 6 of Chapter 1, Sections 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, and 1043.8 of Article 5, Sections 1044, 1044.1, 1044.2, 1044.3, and 1044.5 of Article 5.5 of Chapter 2, and Section 1070.8 of Article 2 of Chapter 3, and add Section 1071.1 of Article 4, Section 1043.8.1 of Article 5, and Sections 1043.9, 1043.9.1, 1043.9.2 of Article 5.1 of Chapter 2, and Repeal Section 1044.4 of Article 5.5 of Chapter 2 of Division 10 of Title 16 of the California Code of Regulations

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

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

Staff Recommended Response:

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

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

Board proposes to make the changes proposed by the commenter for sections 1043(b), 1043.9(b), and 1044(a).

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

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

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

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

Staff Recommended Response:

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

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

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

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

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

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

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

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

Comment Summary:

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

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

Staff Recommended Response:

Reject Comments:

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

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

> The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care facility administration and the appropriate

committee, and at the discretion of the physician, dentist or podiatrist. If a general anesthetic agent is administered in a dental office, the dentist shall hold a permit authorized by Article 2.7 (commencing with Section 1646) of Chapter 4 or, commencing January 1, 2022, Article 2.75 (commencing with Section 1646) of Chapter 4.

However, this provision is not part of the Dental Practice Act, relates to the provision of anesthesia services by nurse anesthetists in acute care facilities, and simply addresses the requirements for administration in a dental office, which is only one type of outpatient setting. According to Board Regulatory Counsel, this provision does not expressly or impliedly supersede the requirements in BPC section 1646.1. To the extent the commenter is suggesting amendments to existing section 1043(b) or changes to BPC section 1646.1, the comments are rejected as neither not sufficiently related to this rulemaking or requiring statutory changes that are beyond the authority for the Board to address in this rulemaking.

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

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

Staff Recommended Response:

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

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

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

The commenter argues that the Dental Board of California should have regulatory oversight for dental offices but not over ASCs that the commenter states are held to a much higher standard for patient safety by their own regulatory entities. The commenter states that any dentist working in an ASC would be under the purview of the Dental Board but the ASC is not. He further asserts that if ASCs are not exempted from the regulations for SB 501, it will

significantly impact the number of patients that are able to be seen due to the severe lack of anesthesia providers who have anesthesia permits from the Board.

Staff Recommended Response:

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

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

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

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

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

accredited ASCs be exempt from the proposed regulation, proposed amended language, and the current law.

Staff Recommended Response:

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

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

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

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

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

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

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

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

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

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

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

Staff Recommended Response: The Board rejects these comments for the following reasons. It is unclear from this comment what specific area the commenter recommends be amended or addressed. It appears that the comment advocates for the Board to authorize CRNAs to perform general anesthesia for pediatric dental patients in an ASC. However, the Board’s authority to authorize the order or administration of general anesthesia to pediatric patients is limited to dentists and physicians licensed by the Medical Board of California (BPC, §§ 1646.1, 1646.9). This comment must therefore be rejected as beyond the authority of the Board to address in this rulemaking.

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

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

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

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

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

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

(1) California Business and Professions code section 1646.18 does not apply to services performed in a Medicare-certified ambulatory surgery center;
(2) A dental ambulatory surgery center is not subject to the jurisdiction of the Dental Board if it is an outpatient setting subject to general anesthesia requirements under the Health and Safety Code;
(3) the dental anesthesia permit requirements set forth in Section 1646.1 do not apply to services provided outside of a dental office; and,
(4) CRNA's may deliver general anesthesia at a Medicare-certified ambulatory surgery center by dentist's order without having a dental anesthesia permit.

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

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

Staff Recommended Response to Comment No. 1: Reject the comment. The Board's current authority for mandating a permit to order or administer anesthesia or sedation is

based upon whether the dentist is performing the procedure on an "outpatient basis" (see BPC, §§ 1646.1, 1647.2, 1647.19, and 1647.31). The words "outpatient setting" occur in existing text in Article 5 (without definition) and as a proposed additional definition to Article 5.5, section 1044(b) for "outpatient basis" as follows:

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

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

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

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

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

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

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

Staff Recommended Response to Comment No. 2: Reject the comment. The Board is not asserting, through this rulemaking, authority to regulate ambulatory surgical center settings. The Board regulates dentists' administration of anesthesia and sedation on an "outpatient basis," which includes under existing regulation, administration in settings other than a general acute care hospital (see current subsections 1044(b) and 1044(a)). The Board's regulatory action to implement relevant statutory provisions is not "underground" but rather existing law and regulation. The Board has statutory and regulatory authority over dentists administering or ordering the administration of general anesthesia or deep sedation, moderate sedation, oral conscious sedation (adults), and pediatric minimal sedation to dental patients on an outpatient basis, which includes treatment at ASCs that are considered an outpatient setting by law (see BPC, §§ 1646.1, 1647.2, 1647.19, and 1647.31; current Cal. Code Regs., tit. 16, §§ 1043(b) and 1044(a); and HSC, §§ 1248.1(a), (f)).

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

With respect to the comment requesting exemption from regulations, the Board presumes the comment is directed to possible changes to sections 1043(b) or 1044(a). As explained in the response to comments B.1., B.2., C., and D. above, to the extent the commenter is suggesting amendments to existing sections 1043(b) or 1044, it is rejected as not sufficiently related to this rulemaking. The regulatory proposal to add new subsection 1043.9(b) simply restates the Board's existing authority for pediatric patients receiving oral conscious sedation at section 1044(a). For the reasons discussed in more detail below, the Board wishes to retain this long-standing interpretation of outpatient basis for the newly

titled “pediatric minimal sedation permit” (previously pediatric oral conscious sedation permit) that the Board believes has worked well to ensure public protection and to maintain consistency with the “outpatient” and “outpatient basis” definitions contained in sections 1043 and 1044. Consideration of possible changes to section 1043.9 and not the others would lead to inconsistent regulatory oversight. For these reasons, the comments are rejected.

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

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

Staff Recommended Response to Comment No. 3: Reject the comment. As explained in the response to comments B.1., B.2., C., and D. above, this proposed comment is not sufficiently related to this rulemaking. The Board also considers the following substantive legal and policy issues regarding this existing regulatory definition.

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

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

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

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

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

Finally, when the Board last considered revisions to section 1043(b) in 2006, the Board was asked by the California Association of Nurse Anesthetists (CANA) to consider a similar issue and exempt facilities accredited by an accrediting entity approved by the Medical Board of California (see p. 3 of Exhibit "E" Final Statement of Reasons attached to written comments provided by Andrew Kugler) and was advised by Board counsel at the time that the requested changes would be inconsistent with the statute. Current Board Regulatory Counsel does not disagree with that assessment and advises that revising the definition for "outpatient" as recommended would require amendments to the Dental Practice Act.

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

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

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

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

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

> (b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility which is a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

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

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

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

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

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

(a) “Outpatient basis” means a dental office where oral conscious sedation is being provided to dental patients with the exception of a treatment facility which is a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the California Department of Health Services as a “general acute care hospital” as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, section 1044.4 will be retained, **and not repealed**. Applicants seeking to meet the requirement of BPC section 1647.20(d) – 10 cases or oral conscious sedation satisfactorily performed by the applicant within any three-year period ending no later than December 31, 2005 – can still use Form OCS-4 (03/07) to document those cases.

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

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

1043.3. Onsite Inspections
All ~~offices~~ outpatient settings in which general anesthesia, deep sedation, or moderate sedation is

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

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

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

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

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

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

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

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

The commenter proposes changes to section 1043(b), 1043.9, and 1044(a) to exclude the following new types of facilities from the definition of "outpatient" and "outpatient setting": (1) licensed by the California Department of Public Health as a "surgical clinic" pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health & Safety Code; (2) accredited by an accrediting agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 128); or (3)

certified to participate in the Medicare Program as an ambulatory surgical center pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

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

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

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

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

Repeated comments:

(1) Comments requesting further exemption for anesthesia and sedation in outpatient settings that include ambulatory surgery centers: Jeanne Vance, Bryan Docherty, Monica Miller, Mary Wilson, Michael Warda, and Ken Pierson each echoed the suggestion found in many written comments that ASCs be exempted from the regulations defining outpatient or outpatient settings.

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

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

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

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

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

DENTAL BOARD OF CALIFORNIA

FINAL STATEMENT OF REASONS

Hearing Date: May 31, 2006

Section(s) Affected: 1044, 1044.1, 1044.2, 1044.3, 1044.4 and 1044.5

Updated Information

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

Current regulations include OCS-5 (rev 10/99) and OCS-3 (rev 10/99), which should be removed and replaced by OCS-6 (03/07), OCS-3 (03/07) and OCS-4 (Rev 03/07), incorporated by reference.

A typographical error in Section 1044(d) referencing the FDA as the "Federal Drug Agency" has been corrected to "Food and Drug Agency".

Local Mandate

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

Small Business Impact

This action may have a slight adverse economic impact on less than 100 dental offices that operate as small businesses.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Objections or Recommendations/Responses

The following recommendations and/or objections were made regarding the proposed action:
(1) Section 1044(a) refers to exempt settings accredited by the Joint Commission on Accreditation of Health Care Organizations (JAHCO). The California Dental Association (CDA) asked the Board to clarify that the only exempted JAHCO settings should be those that are acceptable for providing oral conscious sedation services. CDA suggests that this subdivision should be amended to read "a treatment facility which (that) is accredited as an office-based surgery facility by the Joint Commission on the Accreditation of Health Care Organizations...."

This recommendation was considered by the Board, who agreed that a complete analysis of the JAHCO standards may need to be done. However the board noted that the JAHCO exemption has been in the minor OCS regulations from the beginning and that the currently proposed regulations may be delayed while staff is researching this issue. Based on the testimony from the hearing, a delay in implementing these regulations will lead to patients not seeking badly needed dental care. The Board decided to preserve the current language and ask staff to research the issue and report back to the Board at a later date.

(2) CDA proposed modified language to clarify what constitutes a single maximum dose as referred to in Business and Professions Code Section 1647.18, following:

> "Oral conscious sedation" means a minimally depressed level of consciousness produced by oral medication that retains the patient's ability to maintain independently and continuously an airway, and respond appropriately to physical stimulation nor verbal command. "Oral conscious sedation" does not include doses less than or equal to the single maximum does that can be prescribed for home use."

The Board agreed to adopt proposed modified text to be added under Section 1044. Definitions, subsection (d) as follows:

> "For the purposes of adult oral conscious sedation, administering a drug to a patient in a dose that exceeds the maximum recommended does as established and listed by the United States Food and Drug Administration (FDA) on the drug's FDA-approved professional labeling insert or packaging information shall be considered exceeding the single maximum does that can be prescribed for home use."

(3) Written comments from the CDA asked that the board specify the evidence of completion required by Section 1044.2. The board agreed with this comment and adopted the suggested modified text as follows:

> "A dentist must submit a copy of his or her certificate of completion from a board approved educational program as defined in Section 1044.3 or diploma from a recognized dental residency or post-doctoral program as defined in this section."

(4) CDA believed that the proposed language under Section 1044.3 should be amended to clarify that a board approved education program in OCS must be exclusively geared toward teaching either OCS for adults or OCS for minors and should not be allowed to be a hybrid course for the two. The Board agreed with this comment and adopted modified text to Section 1044.3(b) as follows:

"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."

(5) CDA's final written comment noted that proposed section 1044.5 states "All equipment must be age-appropriate and capable of accommodating patients of all sizes" could be interpreted to mean that a holder of a minor OCS permit would need to have related equipment that accommodates adults, while a permit-holder administering OCS to adult patients would need to have equipment appropriate to minors. The board agreed with this comment and adopted modified text to Section 1044.5(a)(5) as follows:

"All equipment must be age-appropriate and capable of accommodating the patients being seen at the permit-holder's office."

(6) A written comment from Paul Coleman, DMD, recommended following the guidelines outlined by the American Dental Association, and spoke against any guidelines that would set up barriers for the dental phobic as being detrimental to the dental health of the citizens of California. The board considered this comment and determined that it contained no clear recommendations.

(7) A written comment from Dr. Steve Austin asked, "If you must adopt regulations, then simply require the types of training, documentation and monitoring that the DOCS (Dental Organizations for Conscious Sedation) group recommends." The board noted that the proposed amendments are necessary to allow the issuance of permits to administer oral conscious sedation of and include input from the DOCS group through the regulatory process.

(8) A written comment from George Koutsoukos, DDS, CAGS, MSc, stated that "the upcoming legislation should ensure proper training and careful screening for Adult Oral Conscious Sedation." Dr. Koutsoukos proposed no specific modifications to the existing proposed language. The board agreed with this comment.

(9) A written comment from Dr. Daniels C. Thirlwall, DMD encouraged the board to "listen to the representatives from the DOCS organization and adopt their criteria as California standard of care." The board considered the DOCS protocols and decided not to reduce the existing requirements for 25 hours of education including a clinical component utilizing at least one age-appropriate patient.

(10) Dr. Jerry Massimei wrote "I would recommend that the Dental Board establish regulations that are in compliance with the American Dental Association's guidelines on the matter. I am pleased that the Dental Board is incorporating into its guidelines a Grandfathering clause so that I do not have to go through any further training than the mountain of training I have already had. A simple documentation of a few cases (say five) would be quite adequate to protect the public on a technique that has exhibited its safety." The board rejected these comments as the proposed amendments follow the

guidelines of the American Dental Association and Section 1647.20(c) allows for "grandfathering" on the basis of ten cases, not five.

(11) Dr. Thomas J. Gass, DDS, emailed that "I am in favor of the use of oral conscious sedation as detailed by the letter you received from the president of DOCS (Dental Organization for Conscious Sedation), Dr. Michael Silverman." The board considered the comments of Dr. Silverman and voted to retain the same California requirements for adult oral conscious sedation as for minor oral conscious sedation to ensure the protection of the public and the intent of the legislation.

(12) At the regulatory hearing, Dave Cutts, DDS, stated that he was definitely in support of the regulations including the requirement for 25 hours of education including one live patient requirement.

(13) At the regulatory hearing, Chris Wong, DDS, Alice Moran, DMD, Ginny Kornspan, Albert Silvera, DDS, Brett Peterson, DDS, Roger Kurthy, DMD, Eugene Pester, DDS lecturer for DOCS, Ricardo Perez, DDS, Sean Thompson, DDS, Ken Whelan, DDS, Devon Hocker, Sun Costigan, DDS, Kirk Petersen, DDS and Michael Silverman, DMD, DOCS representative all spoke in support of modifications to Section 1044.3 to require 18 hours of didactic with 20 clinically oriented experiences as the current program administered by DOCS is structured.

The board rejected these comments and decided not to reduce the existing requirements for 25 hours of education including a clinical component utilizing at least one age-appropriate patient for public protection. The board unanimously agreed that there is no substitute for a live patient experience within the educational process for obtaining an oral conscious sedation permit and voted not to reduce the requirements as currently specified in Section 1044.3.

Comments regarding the 15-day Notice of Modified Text

There were no comments concerning the modified proposal.

State of California Department of Consumer Affairs

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REGULATORY HEARING
Department of Consumer Affairs
1625 North Market Blvd, Hearing Room S-102
Sacramento, CA 95834
May 31, 2006
MINUTES OF PUBLIC HEARING FOR SECTION 1044
Oral Conscious Sedation

Staff Present:

Robert Hedrick, Executive Officer
Donna Kantner, Regulations Analyst
LaVonne Powell, DCA Legal Counsel

Title 16, California Code of Regulations, Amend Section 1044 – Oral Conscious Sedation

Executive Officer Hedrick read the opening statement explaining the hearing process and opened the hearing for testimony at approximately 10:00a.m.

Dave Cutts, DDS practitioner in Temecula for 22 years, spoke in support of the regulations with possible modifications to the current requirements of 25 hours of didactic training and 1 live patient experience. "I have performed over 3,500 IV and then, conscious oral sedation cases over the years without incident. I hope that my comments will assist the board in carrying out your mission in safeguarding and forwarding the best interests of the people of this great state. In my early years of practice, I witnessed the implementation of much needed regulations in control of IV conscious sedation, and the positive effect that this had on the safety and quality of care that my profession delivers to the people of this state. This took place in response to a very real and urgent situation. I remember it well as my desk in the Oral Surgery Department at Loma Linda University, where I was a volunteer in the undergraduate clinic once a week, sat next to some of the professors who were a part of the evaluation process, and made recommendations to this board. They assessed the problems and made recommendations on the requirements necessary for IV conscious sedation licensure. I recall this to you now, because I wish to point out that, while there are some similarities between then and the situation today, in terms of necessity in that the board is again asked to carry out its mission in determining the necessary steps to safeguard the public. At the same time, there are also significant differences that I'd like to bring up.

The time has come for the regulation and standardization of oral conscious sedation in this state, there is no doubt of that. It is a needed and overdue thing. I suggest that these standards and requirements be appropriate to the situation. So, what is the situation? This is where I see a major difference from the last time this board acted to regulate sedation. Unlike the past situation, conscious oral sedation, performed on adults within the parameters established by the Dental Organization for Conscious Sedation has resulted in zero incidents after one million procedures nationwide. That is an astounding record. This is a difference.

The other major difference that I see is equally significant when the issue of serving the public's health is kept in mind as the goal, and that is the goal. The amount of dental disease treated and lives bettered in my practice because of the availability of conscious oral sedation is an amazing story, even to me. Add to this the fact that it is clear that the percentage of untreated dental disease due to avoidance based on outright dental phobia and fear, then one starts to get the idea of how large and important this issue truly is. I sincerely wish that I could have brought one or more of my high fear patients here today so that you could hear directly from them. My average oral conscious sedation patient or typical conscious oral sedation patient has not seen a dentist in 8 to 10 years, and that was most likely for emergency treatment. Consequently, their oral health, and often their general health, is severely compromised. They usually are missing multiple teeth, have been in pain for years, and have significant long-term infections that affect not just their dental health, but their overall health. And that doesn't even begin to address the social and cosmetic aspects of dentistry. This is the norm, not the exception. It is not unusual for the patient to break down and cry when describing their last dental experience. In short, this is a public health issue that I believe is much larger than might have been believed in the past.

This is the second difference between the past regulations. The sheer amount of public benefit and good being done by oral conscious sedation. And by that I mean IV conscious sedation was not in widespread use 20 years ago. And the elimination of public access to it did not have significant effect on the overall public health, in my opinion. Since time is limited here, I will speak directly to the point. I believe the regulations and standards that will be considered should reflect the facts of the situation, the necessity of the situation. I believe that they can be implemented in such a way to protect both the public's interest and allow for the continued broad public access. I believe that Dr. Michael Silverman and his colleagues at DOCS have done a tremendous service for our profession by 1) Establishing the first widespread standard for pulse oximeter use by the general practitioner, 2) Establishing consistent medication protocol, 3) Teaching sound pharmacological principles, and 4) Providing and promoting advanced life support training. This did not exist for the general dentist, and even for the specialist in this state before. I can personally testify to the fact that it did not exist, because I went through the training, and it significantly raised the level of my competent service to my patients. I thank you for your time today, and for your service to the people of this great state."

Executive Officer Hedrick asked for clarification as to whether Dr. Cutts was in support of the 25 hours and 1 live patient requirement. Dr. Cutts responded, " I most definitely am in support of it. In my experience, being an experienced IV sedation and oral sedation dentist, then going through and having my professional competency raised, I support it even more."

The next speaker was Chris Wong, DDS, "I am a dentist from Fresno, California and serve the heart of the Central Valley here in California. I wanted to make my comments brief. A lot of what Dr. Cutts spoke of I echo in terms of what I have seen in being able to have access to care through oral conscious sedation. My position on 1044.3 is that I agree with that, but with some modifications. I believe that 18 hours with 20 clinically oriented experiences. Having one age-appropriate patient may not be enough. Doctors can receive a lot of education through a number of videotaped experiences and see a lot more variation versus having only one patient live. I believe it is more appropriate to have going through the process of sedation, you're able to see a lot more of a range of issues. My comments in relation to this is in part based on my experience through DOCS and the fact that I have seen in my years of providing care through oral conscious sedation that I do have through that education a wide range of patients and an understanding of what's needed. Safety is very much a big part of what is emphasized through the DOCS educational experience. Also in terms of what was previously mentioned through the different monitoring systems that we're providing care through this experience through this education that we're able to see a lot of patients that normally wouldn't be able to have access to care. It is my understanding as I treat patients that most of these patients who choose to be orally conscious sedated wouldn't normally come to the dentist. A lot of them haven't come for many years, some 5 to 10 years. A lot of them have fear not only of the pain issue, but the needle issue and so I think you understand that having an IV is can be for some people as much of a fearful factor. I'd like to defer the rest of my time to Dr. Silverman, who I believe will speak later."

Alice Moran, DMD, "I'd like to give my story, since I think it might be a little bit different than some of the other people in the audience. I have signed up to take the DOCS course, but I haven't taken it yet. However, I've been providing oral conscious sedation for the last 15 years in my practice. I was trained by the Navy in Bethesda, I'm a periodontist, and I was at the forefront of the original research and I knew Dr. Ray Dione who had done the initial research for using triazolam for oral sedation. In my experience it's been extremely safe, I've never had any adverse outcomes, and I have been able to treat just a whole host of patients. The other doctors alluded to patients who do not want IV sedation because they are afraid of needles. The other issue is cost and practicality, and for some of these patients who have to come back for repeated treatment, affordability. I think the group of us, if I may speak for everybody, represent a group of real caring dentists who want to be able to make this type of quality dentistry available for more of our public. I just think this has been a tremendous experience for myself, when you see these patients after you've treated them, and people crying, telling you about their dental experiences. They have such a positive experience, and I think another benefit with using triazolam, is a little bit of the amnesia, because we all know as dentists that there are times when you have to hurt a patient. You don't want to, but at that time you have a hot tooth that you can't totally get numb or you just have a traumatic experience where it's a difficult extraction. Those patients come back and it's been a wonderful experience and they just want to come back again.

In terms of the proposal, I would agree with Dr. Wong, that it's more practical and a better learning experience to go with the 18 hours and the 20 cases. That's really all I have unless you have questions for me."

Legal Counsel LaVonne Powell asked how many live patients she felt would be adequate. Dr. Moran replied, " I guess I would defer to Dr. Silverman on this question, because he had come up with an alternate proposal that I think would also be more practical and be a better learning experience."

Ginny Kornspan, "First, I want to say that I'm NOT a dentist. I am a person who is afraid of dentists. And I'm appalled that this is actually being brought up here. Because my fear of needles is something that I personally had to fly up here and explain to you. First of all, I am highly allergic to any anesthesia that anyone would give me through an IV. Any surgeries that I have had have been a horrifying experience. So now to be told that there is a slight chance that I can't get my dental done with this halcyon pill is overwhelming to me. I had a problem where I had to have a tooth extracted. I lived with that pain for 2 ½ years because I was too afraid to have it pulled with an IV sedation. I then met Dr. Moran, who finally explained to me that there was an alternative. She explained that if she gave me this pill, I wouldn't have to go through the needle, I wouldn't have that experience, and I would leave with a more positive feeling towards dentistry. I took that route and I took that chance. And I think you need to hear from people like me, who can explain to you that a dentist should be able to do this, that it is something that all patients need. Number 1, I don't think I could have afforded $500 every time I came in to be IV sedated for all the dental work that I've had done. So I think that you need to hear from the public and see that this is the best course of action for a patient. I didn't remember the extraction, I didn't remember the fear, and now I can go ahead with all my treatment. And that's all I wanted to say."

Albert Silvera, "Good morning. I'm Albert Silvera and I'm a dentist who practices in Los Angeles. My specific comments are perhaps a little repetitive, but in reference to 1044.3, I do support the recommendation with the modification that the DOCS course be given strong consideration for satisfying the requirements for education and patient experiences. I went to the DOCS course a few months back, and it was far and away the most comprehensive course I could have ever imagined on the subject, and I'm someone who goes to continuing education almost once a month. I've been to courses where in one day they'll teach you how to do crown lengthening or implant placement or surgical procedures and it's amazing that they can even do these things in one day. In the three days that I spent in this DOCS course, I was so floored by how comprehensive this course is and all the patient experiences added to my confidence so that I could walk into the operatory and perform the procedure. I'll say that no other course or class has better prepared me for mastering the subject matter at hand, and handling any emergency or anything that might come up. All 20 hours of this course went toward further understanding of an incredibly safe protocol that they have been promoting: there's pharmacological aspects, there's patient care aspects, pre-op, post-op, legal aspects and emergency handling – this was one comprehensive course. There is not three hours of how to market the situation, it was really just fantastic. And the patient experiences were like you were there! I mean, it was every kind of patient, they had patients with medical complications, patients with high fear, low fear, overweight people, all different kinds. It was just very comprehensive, and I feel more competent coming out of this class doing this protocol than any other course that I've walked out of even within

general dentistry. It's an accessible course, it's a thorough course and it's an effective and safe protocol. I'll tell you one last thing, there were probably about 1,000 doctors at this course and I think many of them walked out, if nothing else, to get a defibrillator for their office and be more safe just because of that alone."

Legal Counsel Powell asked how 1044.3(b) would be rewritten to conform to the DOCS course.

Dr. Silvera, "I think the course was about 18-20 hours of didactic of a total 24 hour course, and 20 video patient experiences. There was no live patient experience, but I'll reiterate that the 20 video experiences were far and away better than any one single live patient that could have been imagined. Thank you"

Dr. Brett Peterson, "My name is Brett Peterson, I've been practicing as a dentist for about 21 years here in Sacramento and it's a pleasure to be able to be in front of you and express my views. At the risk of repeating, my position would be to change Section 1044.3(b), to change that from 25 hours of instruction and 1 live patient to possibly 18 hours of instruction with at least those video experiences, and as far as the quantity, he said 20, we certainly get that and it does give you an opportunity to see an extreme variety of types of patients, different types of complications that you could need to consider. With regard to the DOCS courses, I've taken all three of the DOCS courses within the last 10 months, which is over 60 hours of instruction, and involves not just the general oral conscious sedation and anxiolysis procedures but also more advanced ones dealing with people with medical complications, and other things that need to be considered, as well as their advanced cardiac life support, all in an effort to do what you folks want to do, which is bring more safety to the public and ensure that. That is by far our goal, to ensure that the care we give our patients is the very best care, and in doing so we become better dentists ourselves and it's more fulfilling as well. One thing I'd like to speak on is how these regulations, which became effective the first of the year, affected my practice and my patients. As of the first of the year, I was no longer allowed to do conscious sedation without a certificate or permit, and we applied in December and were waiting to hear. Between the first of the year and the time we actually got that certificate, which was sometime in March, we had to delay numerous patients because they only wanted to be treated with conscious sedation. I know of one person who I had treated last year with conscious sedation, an extremely high fear patient, and I remember talking to her at the beginning of January when she needed additional treatment and she said 'whatever you say, doctor, I trust you guys now, you've taken good care of me'. I wasn't able to provide the conscious sedation for her, and I haven't seen her since. I hope that I will have the opportunity to finish her care, and she is in need of care. There was another lady, all ready to go, who said "If only I could get this all done and not strung out over a long period of time," this lady had waited six years since her last visit. Again, that was probably just an emergency visit. She was ready to go, she would sign up, she said 'If you could get me in tomorrow, I'll do it,' and I said I have to wait until I get the permit, and I have not seen her since. More than the impact that this has had on my business, which was significant, I must admit, not being able to do conscious sedation for close to three months, I'm more concerned with the impact that it has had on my patients. We have been delaying this type of care, or we delayed that type of care until I got my permit. I am amazed

though, it's not just that population of high fear patients that have been delaying dentistry for so long that conscious sedation appeals to. I talk about it all the time with my existing patients when they come in and I am amazed at how many say, 'You mean I might possibly take advantage of that too?' We find out that it's not that they hate the dentist, they just dread getting the work done. One good friend, I've known her for 16 years, has been stringing out her appointments just a little bit at a time, just when she had to do something. She finally got introduced to conscious sedation and said, 'Well, let's just get this all done'. She tried it once, finished it up with another visit, and it's people like that that really benefit from all the advances that dentistry has experienced. And all of that was made possible through the DOCS organization. I don't mean to be here just selling their program, but it really does work, it's really dedicated to making the best care available to our patients, and that's what it's all about. Thank you very much."

Roger Kurthy, DMD, "Good morning. This is very important to me on many different levels, like you just heard. First of all, I'm a dentist in Mission Viejo, my name is Roger Kurthy. Oral conscious sedation is not a huge part of my practice, but it is an incredibly important part of my practice. When I was 5 years old, I had major surgery in the hospital, and I got stuck with needles from one end to the other. Back then they didn't have Children's hospital, Mom couldn't stay with you. I have these images in my mind, they have me in a 'big kid' crib, and I remember the nurses literally dragging my Mom out when they were flashing the lights on and off because it was the end of visiting hours. We're talking about 1955. Anyway, I became such a needle phobic, that when I got married and had to have a blood test back in the '70s, I fainted. When I decided to go to dental school, well, first, where's the scariest place to get a needle – it's in your mouth. Well, at least for me it was. And so even though I had never been hurt by my dentist, I became a huge phobic. And when I decided to go to dental school, you would have thought I was Bill Cosby, the laughter throughout all my friends and family was amazing. The only reason I was able to go to dental school was that I was told that we would learn to give injections by giving injections into oranges. And I said, hey, I can do that. My first day in dental school, I found out that we were going to learn by giving injections to each other, and I almost dropped out of school that day. That's the impact that this has had on my life.

I'm not as bad as I used to be because a lot of fear comes from not understanding, not knowing. Now that I do it, I can at least tolerate it, but I think back to the way I was my entire childhood and my early 20s, and again, if I were in that situation, I wouldn't be able to submit to IV sedation, because that's a needle also. Even though this is not a huge part of my practice, it is very important. I was supposed to be on a plane today, going to London, lecturing for a month in Europe. I rearranged my schedule to be here today, even though I may only do two or three cases a month. But those patients are so important, I even brought one of them with me today to talk to you. I'd like to tell you about just a few of them. It's easy to just talk about statistics, and how many people are afraid, but if we don't see their faces, and hear their stories, sometimes it doesn't impact on us. We've all heard that term 'going postal', well you know about the postal workers that were killed, I have a postal worker who is a patient who was in the room where several of his co-workers were killed. He hid behind a table. He has such mental problems right now that he cannot be in a situation, without sedation, where he feels like he is losing control. He came to me on an

emergency, and we took care of him with oral conscious sedation, and he was absolutely amazed at how he was able to do that. I have a patient currently that, again, we're putting off treatment on, that we started treatment before the end of the year. Now he is originally from England, and he has a gag response, not a reflex, but he's one of these patients where you get about this far from his mouth and he starts to gag. He can't control it, he has a hard time brushing his teeth, and he is this close to losing all his teeth. He doesn't want to, but he's never been able to find an alternative. With the oral conscious sedation, using the DOCS method, we were able to do all his perio. We've gotten about halfway through his case. He cannot be treated. He is not one of your typical high fear patients, he's an incredible gagger. The patient that I brought to talk to you today, Devon, when you look at her, you're not going to see some extremely fearful patient that you expect is going to be a high fear patient. She is just an average, normal person that has this fear within her. When I first met Devon in 1993, she had 3 or 4 teeth with areas of decay that required small, little fillings. Well, according to Devon, she couldn't afford to have the dental work done. Every few years she would come in for a cleaning, and she would say "Oh, I can't afford to do this" and her condition was getting worse. When she found out that we were offering the oral conscious sedation, she cam in and she admitted to us that money never really had anything to do with it, and she will tell you that. It was her fear. Those 4 little cavities that she had turned into almost losing 4 teeth, turned into 4 root canals, post and cores and crowns. But at least, finally we were able to save those teeth, but there was so much destruction of those teeth, the prognosis is not as good. The point is, there's millions of people like that out there. And if we're not able to provide this for them, with the type of regulations that we are talking about here, we are really going to do a disservice to the people of this state. As far as agreeing or not agreeing, I tend to be right on the same page as the last couple of dentists that testified on the 1044.3. I think the regulations are good, but I've got to tell you, I took the DOCS course and I lecture a lot, so I know what it takes, and I go to continuing education courses like crazy. I was amazed at how effective they were at teaching us. And having done this technique, I'm telling you that there's no way you could even get 25 live patient experiences and see a problem, if you did, you'd be lucky actually, as far as educationally, because it always goes so smooth. The benefit of the videos is that they videoed a lot of cases, until they got enough cases where they showed actual cases where minor problems came up. And we saw how they addressed them. You could never duplicate that with live cases. You would have to do that with video, and you would have to film an awful lot of them to be able to come up with these problems. So we actually had the benefit of seeing cases where, none of them were major problems, but minor problems, and how they were addressed. And being able to see that just makes you a lot more comfortable. So the regulations, the way the DOCS course is structured right now, with the 20 video cases, I think it would be a shame to go with one live patient. It would just be a disservice, because you're not going to learn a fraction of what we learned in seeing the 20 video cases. I think that's about all I have to say, except thank you for allowing us to be here, and can see by your faces how attentive you are and how you're sucking this in, it isn't just an administrative thing. I can see that this is something that you're thinking about and caring about, and I thank you for that.

Eugene Pester, "I'm Eugene Pester, I'm a general dentist and a dental anesthesiologist from Spokane, Washington. I did train in Southern California but I choose to practice in the great

state of Washington. I also function as an anesthesia consultant and part-time lecturer for the Dental Organization for Conscious Sedation. My thrust, and what I'd like to add is that I serve on my state's anesthesia rules rewrite committee. We're wrestling with some of the same questions there. I was also privileged, about a month ago, to represent the DOCS organization for Committee H for the American Dental Association, and they are wrestling with some of the same issues, so I commend California for taking a hard look at balancing public access with safety. The point I'd like to get across is that California has served as sort of a 'bellwether' state, a lot of other states do follow your regulatory trends, and I'd like to hope that what comes out of this legislative and regulatory endeavor will be a good model. I also came here to tell you that at the meetings where I do some lecturing for the DOCS organization, I'm constantly, people come up to me and they're surprised that someone with dental anesthesia training would be working with Dr. Silverman and the other lecturers. It's not that surprising when you take a hard look at the curriculum, you take a hard look at the quality of the presentation, it's a first rate organization. The 20 patient videos are superbly done. It would be virtually impossible to match that with live performance. A couple of weeks ago in Chicago, they did do one live performance, and it was frankly boring because nobody learned anything. You're better off with the videotapes, whether it's 18 hours, 20 hours, 24 hours – that's a logistic question that I'm not going to weigh in on. I'd just like to encourage you guys to keep public access in mind, I have a fulltime practice dealing with phobic people. We need every tool in the toolbox, we need oral sedation, we need IV sedation, we need general anesthesia. I do them all, they each have a role, and there are people in our profession who try to guard turf, who do try to wrangle things for political advantage. And that is truly unfortunate. Oral conscious sedation is a splendid technique. The DOCS organization does a very fine job in their teaching, thank you for letting me speak.

Legal Counsel Powell asked Dr. Pester if he administered minor oral conscious sedation, asking if DOCS has a course for minor oral conscious sedation, noting that current regulations combine minor and adult oral conscious sedation regulations. He responded, "Well, conscious sedation is a continuum. I don't know, the reason that I recommend the 18 to 20 hours is because that follows the ADA recommendation. Committee H may end up changing their teaching recommendations, but that is currently the ADA's recommended position. That's why the courses are kind of built around that figure. That's not to say that for public interest, California can't come up with their own requirements. How that would impact your legislative mandates, I really don't know. I'm much more familiar with Washington law than California law. Thank you."

Ricardo Perez, "Good morning, my name is Ricardo Perez, I practice in Pleasant Hill, California. I just want to reiterate what everyone else has been saying, I agree with the proposal for 1044.3 with some modification, as they say, with the DOCS course. I've taken a lot of CE units, especially live, hands on patient courses, and every time I come back from those, I'm pumped up, ready to go, and then I get back to reality. This wasn't like this in the course, everybody was perfect. I think this happens a lot, and I think with the videos, we were able to see a lot of different instances of things that can go wrong, even though they're slight, but at least you see it happening. You know what to do, you see what the assistant should be helping out with, what they're looking for, and I think that's very important. Because when we take these courses and we go back to our practice, it's not always the way

we thought it would be. And with just a live patient experience, it's only one patient, and I really don't think we could see as much as we would with the videos. I think there's a lot of patients out there who are really phobic, gaggers, in my practice it's been gaggers that have made the big impact. Taking full mouth impressions when we're doing full mouth rehabilitation, a lot of patients can't handle impressions. The oral conscious sedation has helped us a lot with that. I think the videos and the hours along the DOCS protocol is a great thing. Thanks.

Sean Thompson, "Good morning, my name is Sean Thompson, practicing in San Clemente, California. I've been practicing oral conscious sedation for about the last five years, I'm a DOCS graduate. I guess the main thing, to cut to the chase, I agree that there should be standards, but I'm not so sure I agree with having a live patient. The reason I say that is when I went through the course, the videos were great because you get to see from a different perspective. You get to see what the assistant should be looking for. You also get to see cases that don't go as planned. In the five years that I've practiced oral conscious sedation, I've never had a problem, it's a pretty non-remarkable procedure. One of the things that is shown in the video is giving a reversal agent, which probably most of us will never have to do. Being able to see that given to a patient, and seeing another dentist give that, gives us the confidence to do that, in case we ever have to do that. Now, I doubt that that's going to happen with a single patient. I can reiterate what every doctor here has said. I have patients that I would not be able to treat without oral conscious sedation. I have a patient who cannot even get her teeth cleaned without oral conscious sedation. It's an access issue for the patients and for the doctors who want to offer this treatment to their patients. I have met the board's requirement for the grandfather clause, so I am speaking on behalf of doctors that want to offer this, and patients. It's a huge issue, I see people who walk in with years of neglect, and the reason they are coming to see me is they know I offer it. So I would encourage you to make this as accessible as possible to dentists and patients. Thank you."

Ken Whelan, DDS,"I pretty much echo everyone else's thoughts here, so I'll keep it brief. I am a dentist in Orange county, California, and I am in support with some changes. I think the 18 hours would be sufficient, with the class that DOCS offers now, and the 20 videos would be more than sufficient. I've also been a DOCS member for about 5 years, That's it."

Edmund Carolan, "Edmund Carolan, representing the California Dental Association, speaking in support of the regulations. We're seeking some clarifying amendments to the regulations, and I'll go through them item by item. The first item is 1044(a), which defines outpatient basis, to not include patient care that is provided in a treatment facility that is accredited by JAHCO [Joint Commission on Health Care Organizations]. There are nine classifications of JAHCO accreditation, I know of at least four oral surgery office-based JAHCO accredited facilities in California, there may be more. I don't think that the Board intended to make it as broad as any JAHCO accreditation. FQHCs (Federally Qualified Health Centers) which I know quite well, that's the bar for them to reach, but being a dentist in an FQHC doesn't qualify you to do OCS, so we would seek a clarification on that. Having said that, I couldn't find the actual qualifications for JAHCO for their office-based surgery centers, so I would just caution the Board to look at those to see if in fact, they offer the same qualifications that are needed

for an OCS permit. The second issue we would speak to regarding clarification, is actually not contained in any regulatory language, but is found in the enabling statute, in the B & P Code 1647.18, where it says that oral conscious sedation does not include dosages that are less than or equal to the single maximum dose that can be prescribed for home use. Given that this law went into effect on January 1, we've received quite a few calls from member dentists asking what exactly is a single maximum dose. The one case that comes to mind is a dentist who had a patient that weighed about 300 pounds and had a high tolerance for the use of Valium, and the ADA's therapeutic guide recommended no more than 10 milligrams of Valium in a single dose, yet he said that he gave anywhere from 15 to 20 to the patient. I spoke with Dr. Yagiela, who served as the chair on the blue ribbon panel on which the legislation and these regulations is based upon, and Dr. Yagiela's recommendation is that the maximum recommended dose be that that is established by the FDA, and is included in the drug's FDA approved professional labeling insert or packaging material and information. The third point with regard to lack of clarity in Section 1044. 2, it states that, and this is with regard to completing a CODA accredited post-doctoral dental residency program as meeting the minimum education requirements, it states that a dentist must submit evidence of completion of this requirement to the Board. CDA would like to see exactly what is evidence clarified and we would recommend a copy of the dentist's certificate of completion or diploma from the recognized dental residency program meet that requirement. In Section 1044.3, we think there should be clarifying language that states that an OCS course that meets the Board approval be geared exclusively towards minors or towards adults, that you can't have a hybrid program in those 25 hours and then meet the qualifications. We think that the uniqueness of the patient populations warrants having separate programs. The last comment I have regarding clarity, in Section 1044.5 it states that all equipment must be age appropriate and capable of accommodating patients of all sizes, are you saying that an adult OCS permit holder must have equipment that can accommodate minors? And for a minor permit holder, do they have to have equipment for adults? It's not clear to us. We would like to see that be 'all equipment must be age appropriate and capable of accommodating the patients being seen in the permit holder's office.' I think that does raise some issues around minor permit holders because they can do adults, but possibly putting our heads together we could figure something out. I know this is something the pedo dentists have raised with us. The last thing, not speaking to the clarity, but speaking to a number of the comments that were made before me, if I may, regarding the 25 hours as well as the clinical experience, that recommendation came from the Board's blue ribbon panel on this topic. It's right in their report that the Board should adopt regulations that mirror what is required for minors. That is pretty much what the Board has done here. I know back in November of last year, when this reg language was first put out by the Board for discussion, I know the DOCS program was in attendance at that meeting and there was some comment about this issue of minors and adults and the clinical experience. The issue came up for airway management for the minor patients, and I know the Board president at that time, Dr. Gordon, went back and checked with Dr. Yagiela and I believe that Dr. Yagiela also thought that adults should have the clinical experience. This is not to say, I'm sure all these people here, the doctors who are here supporting this obviously, are making a pretty compelling argument, but I would just encourage the Board to check with the former chair of the blue ribbon panel on this issue to see if there is any flexibility with these regs in addressing the issue that many of these dentists have brought here today. Thank you."

Michael Silverman, DMD, "Good morning. Thank yoou so much for hearing all of our testimony. As you can tell, our DOCS members who are here are extremely passionate about caring for the fearful population in the state of California. I'm Dr. Michael Silverman, I'm the president of the Dental Organization for Conscious Sedation, and during the last six years, I've had the honor and privilege of teaching and instructing over 6,000 dentists in the use of oral sedation in treating adult patients. And I want to make that clear, that our organization and our teaching is about adults, not about minors. Right now there are presently 461 DOCS members in the state of California, and I sit before you representing those 461, of which you have already heard testimony from seven of them. The first thing I'd like to address, although this may not be the time to address it, so you may stop me at your will, is actually having to do with Section 1647.20(c) which is the board-approved courses. And it's the application that DOCS has submitted to the board to have our program approved, as a board-approved program under that section of the approval language. And what's important for me is not to make claim as to whether you should approve it or not, because I think it's self-evident that you should. But it is to explain to you some of the modifications made to that course to meet the proposed language, although we're going to make recommendation of modification to the language, even though the course has already provided the extra 2.5 hours, for a total of 25 hours. The course is 22.5 didactic hours, it is 20 video patient experiences, described as 'clinically oriented experiences, which may include either supervised administration or group observation on patients undergoing oral conscious sedation.' And we provided one live patient experience at that last program, which we've done in the past before, and we've found that the education surrounding it was less than the videotapes. So we eliminated it, which also allowed us to keep the cost of the program down. I will refer back to the reasons, with regards to first of all, the consideration of alternatives, to be able to make the process less burdensome. First of all, I want to again reiterate that I am in support of the regulations for all of our members, with modifications. And to make those modifications less burdensome, the cost of having one live patient experience at a seminar program is possibly onerous and it would have to be spread amongst the participants. If it had added value to the education, I see no problem with it, But it is not my opinion that it does. And in my experience of teaching courses where we have orally sedated about 60 patients for doctors before, we've eliminated that from our curriculum, and our curriculum just keeps improving, so it's better without them. Therefore we can keep the cost of education less, and allow the practitioners, who have already established an education within the guidelines set forth by your regulations. Let me be a little more specific about that. If a DOCS member has previously attended one of our programs, say within the last three or four months, that did not have that one live patient experience and did not have that extra 2.5 hours to equate to 25 plus the one, and did not have an opportunity to provide 10 documentable cases that that person may have to go back to a brand new program to get that education, which would be quite repetitive and again burdensome on that doctor. That's another reason that we're recommending the changes to Section 1044.3 be to read 'the educational program shall be approved by the board and shall consist of satisfactory completion of 18 hours of instruction and 20 clinically oriented experiences which either may include supervised administration or group observation on patients undergoing oral conscious sedation' as we have in our video experiences. 'The course shall include, but not be limited to the following areas' and then you go along and you

identify the areas, whether the board has crossed out the word 'minor' and just didn't need it, or said age-appropriate. It really feels clear to me that these are two separate situations. That a pediatric sedation is not, children are not little adults, with the sedation. They are a different species, a different genus, they act differently, their anatomy is different, their physiology is different, the way that they breathe is different and airway is one of the most important things to be able to maintain in any sedation. Therefore, the regulation which requires the 25 hours, makes some sense for the pediatric because of the additional need for safety. It is well known within the anesthesia community that pediatric sedation is more risky than adult sedation. Therefore, the differentiation between a 25-hour instruction for pediatric and 18-hour instruction for adults only makes logical sense. The national standard as Dr. Pester had previously testified with the American Dental Association, actually references the language as I read it which was 18 hours plus 20 clinically oriented experiences. I'd be happy to provide it to you. So the way that I see that the regulation can be supportive of the people of California, is that the existing pediatric or 'minor', as you refer to it, regulations obviously stay the same, the modifications within the language as I have read to you just be different for the adults than for the pediatric or the minors. The rest of the language is actually perfectly fine, because clearly it differentiates between what equipment and what education be needed. In a pediatric situation they need to see pediatric patients sedated. In the adults, they need to see adult patients sedated, and in pediatric, they need to have equipment that is appropriate to be able to provide airway maintenance and airway management, that is sized appropriately for the patient. In the adults, they need to have the adult. So, already, one of the other issues that I thought was very curious, in your frequently asked questions on your website, it clearly states that if someone right now is a permit holder for pediatric oral conscious sedation, they need not apply for an adult one. Which somewhat makes sense if they had 25 hours versus 18 they've already been educated more than the adult, which they should be. That's my opinion. The reverse should not be true. We are not recommending that an adult permit be allowed to sedate children, and that's one of the reasons that our organization does not teach that, because it does require more education and a greater depth. And the percentage of success within the pediatric community on oral sedation is poor, at best. Dr. Stanley Malamid, who teaches pediatric sedation at USC claims it's 40% success rate in the pediatric population, and we're near 98 or 99% in adults. That's why people like Dr. Pester place children in general anesthesia to accomplish their sedation, to accomplish their dentistry, because there is only 40% success in that aspect, and if it's not successful, he can put a needle in them and he can intubate them and have a safe environment to have their dentistry done. I do not believe that the two should be equated as they have been here. In closing, I do want to bring it back to the patients. Our doctors have traveled quite a way to be here. One of our doctors had actually rescheduled a trip to Europe for his lecturing tour. We've had patients, and I thought our patient who spoke so far was the most eloquent speaker of everyone. It spoke to the point of what this is all about. Let's create a good, appropriate regulation, for which a dentist needs to have the equipment, needs to have the education to safely provide and understand what limitations there are to oral conscious sedation, because there are limitations. And they need to be able to refer those patients who are outside those boundaries. But lets not forget the access to care for the patients that need it. Presently, in the state of California, there are a number of patients who are admitted into the hospital for tooth infections, odontogenic infection, that never leave alive, because those infections are so severe that they create

medical issues that they can't come back from. Each of those patients were so fearful of the dentist, that they avoided the dentist due to fear. I believe that having the access is important, and having the very good regulations to provide safety for the people is important. I do have the ADA guidelines with me which I would be happy to provide to you as well as just a quick cross out on the Section 1044.3(b), showing a minor change in that language. And there will obviously need to be minor adjustments elsewhere to clearly identify pediatric as one, and adults as another."

Devon Hocker, "Hello, my name is Devon Hocker, I'm a patient of Dr. Kerthy's, and he's mentioned a little bit about my fears before, and how I did have a few minor fillings that turned into root canals and crowns and all that other stuff. I also have to say that the only thing I hate more than going to the dentist is flying, but I did get on the plane to come here because I feel that this is really important. I don't want anything to change so that this isn't available to me. I think that I represent a large population of people who absolutely cannot stand getting dental work done. It's not so much the needles with me, it's the drilling, it's hearing it, it's in your mouth. I think it's just a rotten experience. I don't have a bad experience to relate my fear to, it just exists, like I think a lot of people. My husband, he's a fireman, big, strong guy. Now he sees that I don't have a problem getting a root canal, it doesn't bother me, I'm not fearful to schedule it, I'm happy afterwards, he suddenly now has an interest in getting his dental work taken care of. Which leads me to believe that he's been lying and he's scared too. So, it's one of those things, that everybody is not comfortable admitting what they're afraid of. I would rather cry poor than admit that I don't want to sit there for a couple of hours and have dental work done. Again, my husband, I was joking with him and after I'm done and everything's been corrected, then he can go next and Dr. Kerthy's going to be making a lot of money. But then it also brings up a point, you have to wonder if maybe these regulations, there is a lot of money to be made in this industry. Maybe the oral surgeons want a piece of that. It leads me to wonder if maybe it's more a motivation for financial gain than for actual public safety and health. It's a question that comes to my mind. I don't see how it can be a problem, it's the easiest thing I've ever done, and I think it's also important for me to relay my attitude towards dentistry right now to my children, because you don't need to be afraid. I have no apprehension. In fact, I had two fillings that were really sensitive, and he said we could put the crown on them, but if there's a problem and they're still sensitive, we may need to do a root canal. And I said, just do the root canal. No worries, just go, get it fixed, I don't have any fear. I just don't see why anything should change or become unavailable or have to go get an IV so that someone else can have my case. That's why I'm here. Thank you."

Sun Costigan, "I'm not really prepared for this, but I heard there was this hearing, so I decided to show up today. I am a DOCS graduate, and it has been about 6 years I've been practicing oral conscious sedation for adult patients only. I recommend Dr. Silverman's suggestion, I think that providing a good quality course is a must. I really don't care how many units, I just want to be able to get good training so that we can provide quality dentistry for patients. I think a lot of people have already talked, I want to just explain what kind of patients, I had actually three patients that wanted to come. I understood that you shouldn't bring patients. They were really excited, they were ready to come, but I said let me go and find out what is going on. I had one patient come in and he couldn't even sit in

the chair without gagging, so of course, you cannot really do much. I think a big advantage that we didn't talk about is that small work can be done, we don't have to wait until everything is falling apart 10 years later and we have to provide basically full-mouth restoration. I feel if we can provide small procedures, we can maintain those people without going through all the pain and ultimately large expense, ultimately lose teeth. Also this provides such a positive experience to patients, that now I am at the point where I can maintain them without putting them through sleep dentistry. I think that is a big advantage that I see, that people don't have to be afraid and get their treatment when they need it. They can get their work done as they need it, giving them such a positive experience and self-confidence. I have many patients that would never smile, they were too embarrassed to smile. And now they are all smiles, in fact one of my patients said 'My neighbor said How come you smile so much? I said because I have a beautiful smile.' It gives them self-confidence, it's something we can provide to the general population, especially phobic patients. We must do it, we don't have a choice. If we don't provide this type of care, we basically will not provide the care for a certain population. I think there's a fairly large population, I don't have any study for it, but by looking at my practice, there are a lot of people that are afraid. Thank you."

Kirk Petersen, DDS, "My name is Kirk Petersen, I practice in Riverside county, and I must admit that when I first heard about this hearing that I wasn't going to come. And then I started speaking to a couple of my patients about it, and they were so excited by the treatment that we were able to do on them that I figured that I owed it to them to come. I've been utilizing OCS for about a year and a half, I've been a member of DOCS for about a year, and I've only treated 12 to 14 cases. But in six of those cases, patients told us that they wouldn't have had it done if it wasn't for the OCS. In fact, I brought a letter from one of those patients, which I gave to the woman over there [see following written comments]. Dr. Silverman mentioned patients who die from dental infections, I actually had a patient who was in a couple of weeks ago whose brother, who lives in Nevada I believe, died from a dental infection the week before. And I am sure it would have been easily treated under this method. I feel that we owe it to our patients who are phobic and need to be treated using these methods. Thank you."

Asking if anyone else wished to testify and receiving no response, Executive Officer Hedrick thanked the participants and closed the hearing.

CALIFORNIA DENTAL ASSOCIATION

May 24, 2006

Donna Kantner
Dental Board of California
1432 Howe Avenue, Suite 85
Sacramento, CA 95825

RE: Proposed Regulations to Amend Title 16 California Code of Regulations, Sections 1044, 1044.1, 1044.2, 1044.3, 1044.5 and add Section 1044.4.

CDA

Dear Ms. Kantner:

The California Dental Association (CDA) is writing to provide comments on the proposal by the Dental Board of California (DBC) to amend sections 1044, 1044.1, 1044.2, 1044.3, 1044.4, 1044.4 and add section 1044.4 of Title 16 of the California Code of Regulations (CCR). The proposed regulations, if approved, would implement and provide clarification for a new section of law related to the requirements and standards for dentists who desire to provide oral conscious sedation (OCS) to adult patients. CDA co-sponsored the legislation that has given the Dental Board (the "Board") the authority for adopting these regulations.

While CDA has played an active role in moving this issue forward to ensure the utmost protection is provided to California patients, we have several concerns with the proposed regulatory language. CDA believes that there are several areas in the proposed regulatory language that lack clarity. California Government Code Section 11349 (c) defines clarity to mean "written or displayed so that the meaning of the regulations will be easily understood by those person directly affect by them." Clarity is one of the six criteria that the proposed regulatory language must meet before being approved by the Office of Administrative Law (OAL).

First, CDA is concerned that there is a lack of clarity in proposed section 1044 (a), which defines "outpatient basis" to not include patient care that is provided in a treatment facility that is accredited by the Joint Commission on Accreditation Health Care Organizations (JCAHO). CDA believes a lack of clarity exists in this section because *which type* of JCAHO accreditation is acceptable for providing OCS services without a permit is not defined. JCAHO offers accreditation in 9 areas of health care to include ambulatory care, laboratories, long-term care, office-based surgery facilities and hospitals. We assume the Board is seeking to allow dentists who provide care in JCAHO-accredited office based surgery facilities to be exempt from the OCS requirements (hospitals, regardless of JCAHO accreditation, will be covered by the other portion of this proposed section since all hospitals are licensed by the California Department of Health Services). Therefore, CDA thinks clarification is needed and could be accomplished by adding language that states "…a treatment facility which is accredited as an office-based surgery facility by the Joint Commission on the Accreditation of Health Care Organizations" would define which JCAHO accredited facilities a dentist could perform OCS in without obtaining an OCS permit.

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While CDA is seeking to clarify that exemption from obtaining an OCS permit is limited to those providers working in a JCAHO accredited office-based surgery facility, CDA cautions the Board that a complete analysis of JCAHO accreditation standards should be done. Such an analysis will ensure that standards and requirements for JCAHO approved office-based surgery facilities equals or exceeds the OCS requirements being put forth by the Board. Because the JCAHO standards are not readily available to the public, CDA is not able to attest that the JCAHO standards will provide adequate safe-guards for consumer protection regardless of the patient's age.

Secondly, CDA thinks further clarification of what constitutes OCS for adults is needed. Business and Profession Code Section 1647.18 states that ""oral conscious sedation" does not include dosages less than or equal to the single maximum dose that can be prescribed for home use". CDA would encourage the Board to consider adopting regulatory language that further defines this statement by stating that:

> "For the purpose of adult OCS, administering a drug to a patient in a dose that exceeds the maximum recommended dose as established and listed by the United States Federal Drug Administration (FDA) on the drug's FDA-approved professional labeling insert or packaging information shall be considered exceeding the single maximum dose that can be prescribed for home use."

CDA believes that this definition is needed to ensure that a "benchmark" is established and that no dentist is free to set what he/she considers to be a "maximum recommended" dose. Such clarity will make it is perfectly clear that a dentist who administers a drug at a rate that exceeds the "benchmark" or recommended maximum dose is aware that they will need to be in possession of an OCS permit before performing this duty.

The third point CDA would like to address is the lack of clarity in proposed section 1044.2. This section proposes to recognize the completion of select CODA accreditation, post-doctoral dental residency programs as meeting the minimum educational requirements for administering OCS. This section states that "[A] dentist must submit *evidence* (emphasis added) of completion of this requirement to the Board". CDA recommends that the Board adopt language that clarifies and specifies exactly what evidence must be submitted to the Board for this section. CDA suggest that language be adopted that states "[A] dentist must submit a copy of his/her certificate of completion or diploma from a recognized dental residency or post-doctoral program as defined in this section". CDA believes strongly that regulations should read like instructions and that regulatory language should crafted in a manner that avoids the need for interpretation and thus deters the promulgation of underground regulations.

CDA also thinks that the language under proposed section 1044.3 should be amended to clarify that a Board approved education program in OCS must be exclusively geared

toward teaching either OCS for adults or minors, and should not be allowed to be a hybrid course for these two populations. Section 1044.3(a), as proposed, states that an

instructional program be geared toward "…conscious sedation in the minor or adult dental patient" and this statement could be construed to insinuate that the educational program must be specific to one population. However, CDA would be more comfortable with more specific language to define this point. Given the unique nature of the knowledge and skills needed for providing OCS to these two populations, CDA strongly believes that the minimum hour requirement for program approval be dedicated to a specific age-based patient population.

Finally, proposed section 1044.5(a)(5) states that "[A]ll equipment must be age-appropriate and capable of accommodating *patients of all sizes*" (emphasis added). CDA thinks such a statement lacks clarity because it could be interpreted to mean that a holder of a minor OCS permit would need to have related equipment that accommodates adults while a adult permit holder would need equipment for minors. While a minor OCS permit holder can provide OSC services to an adult, CDA does not think it is cost-effective or practical to require a permit holder to purchase and maintain equipment that will not likely be used. CDA believes that more appropriate language for this section would be to state that all "*all equipment must be age appropriate and capable of accommodating the patients being seen in the permit holder's office*".

CDA looks forward to working with the Dental Board to move these regulations forward. Please do not hesitate to contact me if you have any questions. I can be reached at 916-554-4987.

Sincerely,

Edmund Carolan
Legislative and Regulatory Advocate

From: Lois Richardson
To: Olney, Jessica@DCA
Cc: Wallace, Sarah@DCA
Subject: Proposed regulations: Anesthesia and Sedation
Date: Sunday, January 23, 2022 6:19:55 PM

[EXTERNAL]: [redacted]

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Hello,

I reviewed your proposed regulations on dental anesthesia and sedation. I thought I'd send you a quick email to let you know that:

1. "The Joint Commission on Healthcare Organizations" is now called "The Joint Commission."
2. The state agency that licenses and regulates California hospitals is called the "California Department of Public Health," not the "California Department of Health Services."

In light of this, you may wish to make the following changes to your proposed regulations:

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

- Section 1043.9(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility ~~which~~ that is accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

- Section 1044 (a) "Outpatient basis" means "outpatient setting" as used in Health and Safety Code Sections 1248 and 1248.1 and means all settings where oral conscious sedation is being provided to dental patients with the exception of a treatment facility ~~which~~ that is accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

I hope this is helpful.

Lois

Lois Richardson
Vice President & Legal Counsel
California Hospital Association
[redacted]

From: [redacted]
To: Olney, Jessica@DCA; Wallace, Sarah@DCA
Subject: SB501
Date: Monday, January 24, 2022 10:04:47 AM
Attachments: Letter to the Dental Board.docx

[EXTERNAL]: [redacted]

Thank you for your consideration.

Dr. Mary Ann Wilson DNP MSN CRNA

To Whom it May Concern:

Many ambulatory dental surgery centers treat thousands of pediatric patients every year under general anesthesia. Many of these centers treat patients in an underserved demographic. Most of the patients have severe decay, pain, swelling, and other medical conditions that prevent them from receiving dental treatment in a traditional office setting. Due to the limited amount of pediatric dental offices accepting Medi-Cal and Denti-Cal, these centers are the only access to dental care for this population.

The Indio Surgery Center is in the city of Indio, which is located 23 miles east of Palm Springs and 127 miles east of Los Angeles, California. The population of Indio in 2010 was 76,036. Children under the age of 18 account for 27% of the population. Demographics of the city are 68% Hispanic, 26% Caucasian, 3% Black, and 3% Asian. The average income of the population is $49,555. The ambulatory pediatric dental surgery center is Joint Commission approved and MediCal certified. The center's service area encompasses Riverside, San Bernardino, and Imperial Counties.

In 2021 we saw 2400 patients, all under the age of 12 years old. Of the 2400 patients 95% of the patients are Medi-Cal. We currently have 3 dentists providing dental care, Dr. J. Trammell, Dr. J Park, and Dr. S. Appleton. We have 2 dental anesthesiologists, a medical director that is an anesthesiologist MD and 2 CRNAs. I am the primary provider for the center, as I am there 3 of the 4 days of work. The CRNA's at the center administer at least 60% of the anesthesia between the 3 types of providers. In addition, the CRNA's work currently at an acute JCAHO accredited hospital in the area.

One of the most critical components of operating our ambulatory surgical center is having high quality anesthesia providers. Our patients are pediatric, and some have special

needs. Both populations require the highest level of anesthesia provider who can safely and effectively manage their sedation while the dentist completes their dental work. Our centers have always placed a high priority on the best anesthetists, and it has been a consistent challenge to recruit for this position. One of the best resources we have found to help us fill our need is the Certified Registered Nurse Anesthetist [CRNA].

I'm asking that the Dental Board take into consideration the language of "outpatient" as solely a dental office, thus leaving ambulatory centers as ours except from this language. Without this, the patients we service (as well as the providers) will greatly be affected.

Respectfully,

Mary A. Wilson DNP, MSN, CRNA

GOOD AFTERNOON,

MY NAME IS DR. MARY WILSON, A DNP PREPARED CRNA. I WOULD LIKE TO THANK THE BOARD FOR THE OPPORTUNITY TO SPEAK TODAY ON BEHALF OF MYSELF AS WELL FOR THE CHILDREN OF SAN BERNARDINO, RIVERSIDE, AND IMPERIAL COUNTIES.

MY SPECIFIC CONCERN TODAY IS THE BUSINESS AND PROFESSIONS CODE DIVISION 2

CHAPTER 6 ARTICLE 7 2827:

The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care facility administration and the appropriate committee, and at the discretion of the physician, dentist, or podiatrist.

My request is that the acute care facility language and interpretation to include an outpatient surgery center.

The surgery center in which I am a provider is the city of Indio, which is located 23 miles east of Palm Springs and 127 miles east of Los Angeles, California. The population of Indio in 2010 was 76,036. Children under the age of 18 account for 27% of the population. Demographics of the city are 68% Hispanic, 26% Caucasian, 3% Black, and 3% Asian. The Indio ambulatory pediatric dental surgery center is Joint Commission approved and MediCal certified. The center's service area encompasses Riverside, San Bernardino, and Imperial Counties. In San Bernardino alone the people living in poverty is 26% according to the US Census Bureau July 2021. Indio 16%

In 2021 we saw 2400 patients, all under the age of 12 years old. Of the 2400 patients 95% of the patients are Medi-Cal. We currently have 3 dentists providing dental care. We have 2 dental anesthesiologists, a medical director that is an anesthesiologist MD and 2 CRNAs. I am the primary provider for the center, as I am there 3 of the 4 days of work. The CRNA's at the center administer at least 65% of the anesthesia between the 3 types of providers. In addition, the CRNA's work currently at an acute JCAHO accredited hospital in the area.

Healthy People 2020 defines a *health disparity* as "a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."

One of the most critical components of operating our ambulatory surgical center is having high quality anesthesia providers to provide care to this population that would experience more significant health and dental care disparity if the CRNA providers were denied the ability to administer anesthesia to this deserving population. Our patients are pediatric, and some have special needs. Both populations require the highest level of anesthesia provider who can safely and effectively manage their sedation while the dentist completes their dental work. Our center has always placed a high priority on the best providers. One of the best resources the center has is high quality CRNA's.

I'm asking on behave of the families and children of the 3 counties which I have the privilege to serve that they are provided the health equality they deserve.

Please modify SB501

1. An Accredited/ Medi-Cal certified ambulatory surgery center be exempt from the definition of “outpatient” and that outpatient refer solely to the dental office.
2. An Accredited/ Medi-Cal certified ambulatory surgery center be included with the acute care facilities in section 2827 in reference to CRNA’s.

Thank you for your time

.

From: [redacted]
To: Olney, Jessica@DCA
Cc: Wallace, Sarah@DCA
Subject: FW: Regarding Assembly bill 501
Date: Friday, January 28, 2022 11:18:19 AM
Attachments: Assemby Bill 501.pdf

[EXTERNAL]: [redacted]

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Good Afternoon Jessica, Dr. Ken has ask me to forward along a letter regarding his concerns on Assembly Bill 501.
If you have any questions or concerns please let me know. Thank you,

Tammy Kegler

Tammy Kegler
[redacted]

HAPY BEAR SURGERY CENTER, LLC

Meet "Hapy" - Sleep Happy - Leave Happy

Stress Free Pediatric Sedation Dentistry

Jessica Olney, Staff Services Manager I
Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815

January 27, 2022

Dear Ms. Olney:

Hapy Bear Surgery Center, LLC, has been serving the neediest pediatric patients in the Central Valley of California since 2010. As a state licensed Ambulatory Surgery Center (ASC), we specialize in providing a place for dentists to treat pediatric patients who can't get treated in a regular dental office.

All patients must be referred to Hapy Bear Surgery Center from their primary dentist for either special needs, young age and complicated treatment, or severe phobia. In each case, a dental professional has evaluated the patient and determined that the best course for treatment is for the child to be sedated while being treated. After treatment is completed at Hapy Bear the patient is returned to their primary dental home for their 6-month checkups and continued care.

Since 2010 we have treated over 26,000 patients at Hapy Bear. In 2021, we treated 2699 patients referred to us from 178 different dental offices. We serve the farmworker community in Tulare County and 94% of our patients are covered by Medi-Cal/Denti-Cal.

While the type of treatment being done in our Ambulatory Surgery Center is dental in nature, our facility is actually licensed by the Department of Health and Human Services of California, and we are accredited with CMS Deemed Status by The Joint Commission.

Assembly Bill 501 attempts to allow the Dental Board of California to overstep their regulatory limits by determining the necessary licenses needed by anesthesia professionals working in our Ambulatory Surgery Center. We strongly request that Ambulatory Surgery Centers as outpatient treatment centers be exempted from this bill.

We fully understand that the Dental Board of California should have regulatory oversight for dental offices. But since ASCs are held to a much higher standard for patient safety by their own regulatory entities, the Dental Board should not have oversight of the ASC. Any Dentist working in the ASC would be under the purview of the Dental Board, but the ASC would not.

An ASC should be allowed to contract with any properly licensed anesthesia provider, be that a Dentist with an anesthesia permit from the Dental Board of CA, a Medical Anesthesiologist with or without an anesthesia permit from the Dental Board of CA, or a Certified Registered Nurse Anesthetist (CRNA) licensed in the state of CA. The type of procedure being done in the ASC should not determine the type of license the anesthesia provider must hold.

As things are right now, we have one Dentist Anesthesiologist and several CRNAs providing the coverage we need for our patient flow.

1979 Hillman St. · Tulare, CA 93274 · Ph: (559) 732-4279 · Fx: (559) 636-4455 · www.HapyBear.com

If ASCs are not exempted from AB 501, it will significantly impact the number of patients we are able to see due to the severe lack of anesthesia providers who have an anesthesia permit from the Dental Board. We would effectively have to shut down our center due to lack of anesthesia coverage.

This is an urgent matter for us as a business and for the children in Tulare County who have no where else to go for treatment.

Sincerely,

Kenneth D. Pierson
Medical-Dental Director
Owner

From: [redacted]
To: Olney, Jessica@DCA
Cc: Wallace, Sarah@DCA
Subject: Request for a Public Hearing Regarding SB 501
Date: Monday, January 31, 2022 2:57:46 PM
Attachments: HBSC-AB 501.pdf
Importance: High

[EXTERNAL]: [redacted]

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Dear Ms. Olney,

Please accept this email as an official request for a public hearing regarding the proposed regulatory action for Title 16: Dental Board of CA department of Consumer Affairs regarding SB 501.

I would also like to include in the public comments in regards to the regulations being discussed the attached letter expressing my serious concerns regarding the oversteping by the Dental Board of CA in regards to Ambulatory Surgery Centers that perform dental treatment.

I look forward to my opportunity to speak during the public hearing. Please let me know when that hearing will happen.

Thank you,

Jeremy

Jeremy Pierson, CEO
Hapy Bear Surgery Center
[redacted]
www.HapyBear.com

HAPY BEAR SURGERY CENTER, LLC

Meet "Hapy" - Sleep Happy - Leave Happy

Stress Free Pediatric Sedation Dentistry

Jessica Olney, Staff Services Manager I
Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815

January 31, 2022

Re: Writing Regulation for SB 501

Dear Ms. Olney:

Hapy Bear Surgery Center, LLC, has been serving the neediest pediatric patients in the Central Valley of California since 2010. As a state licensed Ambulatory Surgery Center (ASC), we specialize in providing a place for dentists to treat pediatric patients who can't get treated in a regular dental office.

All patients must be referred to Hapy Bear Surgery Center from their primary dentist for either special needs, young age and complicated treatment, or severe phobia. In each case, a dental professional must evaluate the patient and determine that the best course for treatment is for the child to be sedated while being treated. Once treatment is completed the patient is returned to their primary dental home for their 6-month checkups and continued care.

Since 2010 we have treated over 26,000 patients at Hapy Bear. In 2021, we treated 2699 patients referred to us from 178 different dental offices. We serve the farmworker community in Tulare County and 94% of our patients are covered by Medi-Cal/Denti-Cal.

While the type of treatment being done in our Ambulatory Surgery Center is dental in nature, our facility is actually licensed by the Department of Health and Human Services of California, and we are accredited with CMS Deemed Status by The Joint Commission.

The regulations associated with Senate Bill 501 that are being written at this time are attempting to allow the Dental Board of California to overstep their regulatory limits by determining the necessary licenses needed by anesthesia professionals working in our Ambulatory Surgery Center. **We strongly request that Ambulatory Surgery Centers as outpatient treatment centers be exempted from these regulations.**

We fully understand that the Dental Board of California should have regulatory oversight for dental offices. But since ASCs are held to a much higher standard for patient safety by their own regulatory entities, the Dental Board should not have oversight of the ASC. Any Dentist working in an ASC would be under the purview of the Dental Board, but the ASC is not.

In order to provide general anesthesia, an ASC should be allowed to contract with any properly licensed anesthesia provider, be that a Dentist with an anesthesia permit from the Dental Board of CA, a Medical Anesthesiologist with or without an anesthesia permit from the Dental Board of CA, or a Certified Registered Nurse Anesthetist (CRNA) licensed in the state of CA. The type of procedure being done in the ASC should not determine the type of license the anesthesia provider must hold.

1979 Hillman St. · Tulare, CA 93274 · Ph: (559) 732-4279 · Fx: (559) 636-4455 · www.HapyBear.com

At Hapy Bear right now, we have one Dentist Anesthesiologist and several CRNAs providing the coverage we need for our patient flow. If ASCs are not exempted from the regulations for SB 501, it will significantly impact the number of patients we are able to see due to the severe lack of anesthesia providers who have an anesthesia permit from the Dental Board. We would effectively have to shut down our center due to lack of anesthesia coverage.

This is an urgent matter for us as a business and for the children in Tulare County who have no where else to go for treatment.

Sincerely,

Jeremy Pierson
CEO & Co-Owner

From: [redacted]
To: Olney, Jessica@DCA; Wallace, Sarah@DCA
Cc: [redacted]
Subject: SB501 Concerns
Date: Monday, January 31, 2022 3:27:06 PM
Attachments: FDSC Letter.pdf

[EXTERNAL]: [redacted]

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Jessica & Sarah,

Please see attached letter from Dr. Alan J. Vallarine with Fresno Dental Surgery Center regarding SB501.

Thank you,

[redacted]
Administrative Assistant to Dr. Alan J. Vallarine
Valley Dental Consulting & Leasing
1729 N. Olive Ave. Ste. 15 Turlock, CA 95382
[redacted]

FRESNO DENTAL
SURGERY CENTER

2828 Fresno Street
Suite 100
Fresno, CA 93721
P. 559.263.9648
F. 559.263.9777
dentalasc.com

A Vallarine
Dental Practice

January 31, 2022

Jessica,

First and foremost, we completely agree with the intention of SB 501 to increase patient safety in a conventional dental office setting.

Fresno Dental Surgery Center is concerned that the current language in this Proposed Regulation/Law could have a major negative impact on access to care if not amended. FDSC is not a dental office, we are CMS Certified Ambulatory Surgery Center.

FDSC was established in 2006 providing children's dental services under general anesthesia for the Fresno community. We have safely treated Tens of thousands of children.

FDSC is a CMS Certified Ambulatory Surgery Center that adheres to all highest life safety protocols. We follow AORN nursing and APIC infection control standards. FDSC has seven experienced registered nurses on-site every day to ensure patient safety. We take life safety and infection control very seriously.

We treat the underprivileged and special needs patients referred to us by over 500 conventional dental offices in the surrounding area. Patients are referred to us only after all attempts have been made and documented to try and complete the patient's dental treatment in a conventional setting. 98% of patients treated are covered by Denti-cal and Medical.

Any disruption of Dental services at FDSC would have a dramatic increase in children being referred to emergency rooms that are already overwhelmed. Dental pain and infection are the leading causes for children to miss school.

We are asking that our state licensed and accredited Ambulatory Surgery Centers be exempt from the proposed regulation, proposed amended language and the current law.

Also, please use this letter as our written request for a public hearing on SB501.

Respectfully,

Dr. Alan J. Vallarine

1729 N. Olive Ave., Ste. #15 Turlock, CA 95382

[redacted]

INDIO SURGERY CENTER

Via E-Mail Jessica.Olney@dca.ca.gov

January 28, 2022

Ms. Jessica Olney
Staff Services Manager 1
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, California 95815

RE: BILL SB-501

TO WHOM IT MAY CONCERN:

We are writing to address our concerns regarding SB-501 as it pertains to the treatment of Dental Surgery Centers under the Bill.

While in Article V, 1043B, it appears that Treatment Facilities accredited by the Joint Commission or licensed by the California Department of Health Services are exempt from the "outpatient" definition in the Bill, other sections seem ambiguous. In general, there does not seem to be any differentiation between a standard Dental Office and a Licensed and Accredited Ambulatory Surgery Center. Clearly there are huge differences in the safety protocols, care and oversight requirements between the two. Ambulatory Surgery Centers have to adhere to the same standards as Hospitals/Acute Care Centers do. In fact, both Ambulatory Surgery Centers and Hospitals are regulated by the same agencies, the Department of Health Services (DHS) and Medicare. These agencies conduct surveys of our facility every 2 to 3 years.

To be clear, we are 100% supportive of the Bill's intent of creating the safest environment for the treatment of pediatric patients under general anesthesia and that is exactly what we do.

Indio Surgery Center opened its doors in 2006 and has successfully treated under general anesthesia over 24,000 pediatric patients. Our surgical team consists of a Dentist, Registered Nurse, Dental Assistant and either a CRNA or a Medical or Dental Anesthesiologist. We have a recovery room staffed by Registered Nurses and all personal are trained in BLS, PALS, ACLS and we perform emergency training drills throughout the year.

Close to 100% of our patients have been referred by traditional Dental Offices who are either not experienced to treat pediatric patients under general anesthesia or believe the patient, due to the extensive amount of work needed, would be better suited in a specialized Dental Surgery Center setting. Furthermore, we are one of the few options for Developmentally Disabled (ADHA / Autistic) and medically compromised patients.

Located in Indio, California we treat patients from a wide geographical area covering Imperial, San Bernardino and Riverside County. 95% of our patients our billed through Medical and Denti-cal and this under-served demographic population would lack access to dental care if our facility is negatively impacted.

Without exemption from Bill-501, specifically our ability to utilize CRNAs as part of our Surgical Team, our operations would be drastically effected. Currently CRNAs perform about 62.50% of our surgeries or about 130 cases per month based on 2021 surgery levels. Not only are our CRNAs thoroughly qualified with extensive pediatric experience, but finding Dental Anesthesiologists in today's supply constrained environment has been extremely challenging. It is our understanding that there are no Dental Anesthesiologist Schools currently on the West Coast since Loma Linda University School of Dentistry, a previous source of prospects, shut down their Dental Anesthesiology program in 2019.

Alternatively, finding Medical Anesthesiologists, let alone Medical Anesthesiologists with a Dental GA Permit, who are comfortable with pediatric patients is extremely difficult. This situation has only been exasperated by the Dental Board's freeze on GA Permits.

We see that SB-501 does allow an exemption for use of CRNAs for Acute Care facilities. Given that there is minimal, if any difference in procedures, care and oversight between an Accredited Treatment Facility and a General Acute Care Hospital, we strongly believe we should be given these same rights under the Bill. From a practical and cost standpoint, Pediatric Dental Surgery should rarely, or ever be performed in a hospital.

Given the foregoing, we respectively request that SB-501 be modified to reflect the following:

A) Accredited / Medicare Certified Ambulatory Surgery Centers should be exempt from the provisions of SB-501 and the definition of outpatient should be solely Dental offices.

B) Accredited Ambulatory Surgery Centers should be included with Acute Care Facilities in Section 2827 addressing the use of Certified Nurse Anesthetists.

Thank you in advance for taking our comments into consideration

Very truly yours,

INDIO SURGERY CENTER, INC.

John A. Bonutto

cc: Sarah Wallace, (Dental Board of California) Sarah.Wallace@dca.ca.gov

From: Lori Dean
To: Olney, Jessica@DCA
Cc: Wallace, Sarah@DCA; John Bonutto
Subject: BILL SB-501
Date: Friday, February 11, 2022 10:50:28 AM
Attachments: SB-501 Dental Board Ltr_ISC.docx

[EXTERNAL] [redacted]

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Dear Ms. Olney:

Pursuant to Indio Surgery Center's Request, attached please find a modified letter regarding Bill SB-501 citing the correct Dental Board reference in paragraph 2.

If you have any questions, please contact John Bonutto at [redacted].

Thank you.

Indio Surgery Center, Inc.

INDIO SURGERY CENTER

Via E-Mail Jessica.Olney@dca.ca.gov

January 28, 2022

Ms. Jessica Olney
Staff Services Manager 1
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, California 95815

RE: BILL SB-501

TO WHOM IT MAY CONCERN:

We are writing to address our concerns regarding SB-501 as it pertains to the treatment of Ambulatory Surgery Centers under the Bill.

While in the definition section of the Dental Board's proposed regulatory language for SB-501 Anesthesia and Sedation (Chapter 2, Article 5, Section 1043), it appears that treatment facilities which are accredited by the Joint Commission on Health Care Organizations, **are not** considered "outpatient" for purposes of this bill, there are also sections of the bill that seem ambiguous in this regard.

To be specific, there does not appear to be a clear differentiation between a standard Dental Office and a Licensed and Accredited Ambulatory Surgery Center. Clearly there are huge differences in the safety protocols, care and oversight requirements between the two. Ambulatory Surgery Centers have to adhere to the same standards as Hospitals/Acute Care Centers. In fact, both Ambulatory Surgery Centers and Hospitals are regulated by the same agencies, the Department of Health Services (DHS) and Medicare. These agencies conduct surveys of our facility every 2 to 3 years. While we predominately do dental procedures, we are licensed by the State to do almost any type of surgery.

To be clear, we are 100% supportive of the SB-501's intent of creating the safest environment for the treatment of pediatric patients under general anesthesia and that is exactly what we do.

Indio Surgery Center opened its doors in 2006 and has successfully treated over 24,000 pediatric patients under general anesthesia. Our dental surgical team consists of a Dentist, Registered Nurse, Dental Assistant and either a CRNA or a Medical or Dental Anesthesiologist. We have a recovery room staffed by Registered Nurses and all personal are trained in BLS, PALS, ACLS and we perform emergency training drills throughout the year.

Close to 100% of our patients have been referred by traditional Dental Offices who are either not experienced to treat pediatric patients under general anesthesia or believe the patient, due to the extensive amount of work needed, would be better suited in a specialized Ambulatory Surgery Center setting. Furthermore, we are one of the few options for Developmentally Disabled (ADHA / Autistic) and medically compromised patients.

Located in Indio, California we treat patients from a wide geographical area covering Imperial, San Bernardino and Riverside County. 95% of our patients are billed through Medical and Denti-cal and this under-served demographic population would lack access to dental care if our facility is negatively impacted.

Without exemption from Bill-501, it appears that we would have limited ability to utilize CRNAs as part of our Surgical Team, which would be drastically impact our ability to operate. Currently CRNAs perform about 62.50% of our surgeries or about 130 cases per month based on 2021 surgery levels. Not only are our CRNAs thoroughly qualified with extensive pediatric experience, but finding Dental Anesthesiologists in today's supply constrained environment has been extremely challenging. It is our understanding that there are no Dental Anesthesiologist Schools currently on the West Coast since Loma Linda University School of Dentistry, a previous source of prospects, shut down their Dental Anesthesiology program in 2019.

Alternatively, finding Medical Anesthesiologists, let alone Medical Anesthesiologists with a Dental GA Permit, who are comfortable with pediatric patients is extremely difficult. This situation has only been exacerbated by the Dental Board's freeze on GA Permits.

We see that SB-501 does allow an exemption for use of CRNAs for Acute Care facilities. Given that there is minimal, if any difference in procedures, care and oversight between an Accredited Treatment Facility and a General Acute Care Hospital, we strongly believe we should be given these same rights under the Bill. From a practical and cost standpoint, Pediatric Dental Surgery should rarely, or ever be performed in a hospital.

Given the foregoing, we respectively request that SB-501 be modified to reflect the following:

A) Accredited / Medicare Certified Ambulatory Surgery Centers should be exempt from the provisions of SB-501 and the definition of outpatient should be solely Dental offices and clinics.
B) Accredited Ambulatory Surgery Centers should be included with Acute Care Facilities in Section 2827 addressing the use of Certified Nurse Anesthetists.

Very truly yours,

INDIO SURGERY CENTER, INC.

John A. Bonutto

John A. Bonutto

cc: Sarah Wallace, (Dental Board of California) Sarah.Wallace@dca.ca.gov

From: Lori Dean
To: Olney, Jessica@DCA
Cc: Wallace, Sarah@DCA; John Bonutto
Subject: Addition to Indio Surgery Center"s 1.28.22 Letter to the Dental Board
Date: Tuesday, February 15, 2022 2:20:16 PM
Attachments: Proposed Regulations_Amendments (AB 501).docx

[EXTERNAL]: [redacted]

WARNING: This message originated from the public internet. Do not open attachments unless you recognize the sender.

Dear Ms. Olney:

Please see the attached requested changes to specific Definitions contained in SB 501 which would satisfy our concerns outlined in our January 28, 2022 letter to the Dental Board to be submitted for the upcoming Dental Board hearing on February 16, 2022.

Please add this information / attachment to our previous January 28th submittal letter.

Thank you.

Lori Dean
Indio Surgery Center

PLEASE CONFIRM RECEIPT OF THIS EMAIL.

Ambulatory Surgery Center Proposed Amendments to SB 501 Proposed Regulations

1043. Definitions

(b) For purposes of this article, "outpatient" means a patient treated in a treatment facility that is not: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or the Accreditation Association of Ambulatory Health Care; or certified as a general acute care hospital or an ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed as a "general acute care hospital" as defined in subdivision (a) or Section 1250 of the Health & Safety Code.

1043.3. Onsite Inspections

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

1043.9 Definitions.

(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility that is: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or the Accreditation Association of Ambulatory Health Care; or certified as a general acute care hospital or ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed by the California Department ~~of Health Services~~ofPublic Health as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

1044. Definitions.

(a) "Outpatient basis" means "outpatient setting" as used in Health & Safety Code Sections 1248 and 1248.1 and means all settings where oral conscious sedation is being provided to dental patients with the exception of a treatment facility that is: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or American Association of Ambulatory Health Care; or certified as a general acute care hospital or ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed by the California Department of ~~Health Services~~Public Health as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

From: Robert Orr
To: Olney, Jessica@DCA
Subject: SB501 Statement
Date: Sunday, February 13, 2022 9:30:37 PM
Attachments: SB501.pdf

[EXTERNAL]: [redacted]

CAUTION: THIS EMAIL ORIGINATED OUTSIDE THE DEPARTMENT OF CONSUMER AFFAIRS!
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Jessica,

Please see attachment for a letter in reference to SB501.

Please let me know you received this.....please

Sincerely,
Robert Orr
[redacted]

FROM: Robert Orr CRNA, MS, MBA, BSN
Orr Anesthesia Services
[redacted]

TO: Dental Board of California
2005 Evergreen Street
Suite 1550
Sacramento, California 95815

SUBJECT: SB501 Language and possible damage because of it

Dear Sir/Ma'am

My name is Robert Orr. I am not political or well versed in legislative language. However, I am an anesthesia provider that has been pediatric dental cases for many years and thousands of cases. This new SB501 needs clear language for ALL groups and stakeholders especially the children. We all agree we want all children to be in a safe environment. We also agree that dental offices need the same safety for the children that hospital and ambulatory surgery centers provide. We cannot have non-medical write laws in general terms without knowingly considering that damage that could come from the blanket law. There is a huge difference in the way a dentist office is regulated as compared to hospitals and surgery centers that deal with agencies like CMS.

I have been the Anesthesia Director at the Fresno Dental Surgery Center since September 2012. Our facility has done over 59,000 patients since September 2012 without any patient transfer to a higher level of care for a medical or dental complication. You can see by my CV attached that I have over 20 years of military medical experience and over 26 years of being a Nurse Anesthetist. I have done literally thousands of anesthetics in every type of anesthesia from general, sedation, and regional. In those cases they have ranged in age from neonatal to over 100 years of age plus. Also, in those cases they have ranged from simple dressing changes to severe burn cases on all ages to multiple system trauma and gunshot wounds and from open heart on and off pump to open brain tumors, aneurysms, and hematomas to multiple orthopedic fractures and total joint replacements. With all of my experience, even though I have done thousands of

pediatric cases there is no such animal as a "Pediatric CRNA" specialty where there is a Pediatric Anesthesiologist. So no matter what I have done or can do I can at this point not acquire a pediatric professional title which a lot of non-medical people don't understand.

The facility at Fresno Dental Surgery Center fills a spot and a need that is very special. Because of the training of our dentists and our anesthesia providers we can take care of the healthiest child to some of the more complicated cases medically and dentally. The main hospitals in our area that do pediatric dental cases are Community Regional Medical Center and Valley Children's Hospital. Because of the time it takes to get into one of these facilities for the not so healthy children, these facilities and other dental offices refer their cases to us at Fresno Dental Surgery Center. We do thousands of children per year at our facility to fill a very needed gap between the healthy and not so healthy child that would normally have to wait between 14 - 16 months to be seen at one of the hospitals. The hospitals and other dental offices know and trust we can take care of these patients as evidenced by the referrals even from the children's hospital. If because of language our facility is put in jeopardy of being able to stay open the thousands of children we do each year would then increase the wait at our surrounding hospitals to 18 – 26 months. We all know that a mouth with huge decay and puss cannot wait for literally years to be taken care of.

The reason for the 14-16 month wait at the hospitals is completely economic. Dental does not pay enough for hospitals to give more case time for dental cases. This is why we get referrals from not only dentist offices but also hospitals to include our children's hospital. Fresno Dental Surgery Center sees over 75% Denti Cal/Medi Cal patients which most of the other dental offices and surgical centers prefer not to see because they want to make more money doing anything but dental especially if the patient has insurance. In this we again are filling a large gap in the care of the pediatric dental patients in our valley.

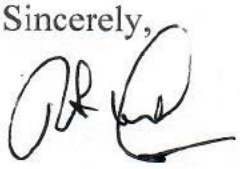
Next a misconception is that CRNA's are not capable of taking care of these cases. As you can see by my history and Fresno Dental Surgery Center's history CRNAs are more than capable of taking care of these kids. There is not enough Anesthesiologist or Pediatric Anesthesiologist to do cases much less do strictly pediatric dental cases. In that same manner there is not a dental anesthesiologist school in California any more so they are fewer in number that the

Anesthesiologist. The dental anesthesiologists I have worked with are not comfortable with complicated medical conditions and syndromes that we can deal with at Fresno Dental Surgery Center. So again we fill a huge gap in the pediatric dental care in our valley.

In closing, again please thoughtfully consider all stakeholders in the wording of this and future legislative actions. Literally thousands of kids can be impacted by SB501 and it won't be in a good way. It will cause a MASSIVE pile up of cases which will cause irreparable damage to a lot of children.

Appreciate your consideration.

Sincerely,



Robert Orr CRNA, MS, MBA, BSN

[redacted]

Robert W Orr, CRNA
[redacted]

I. EDUCATION

A. University of Southern Mississippi, Hattiesburg, Mississippi. Graduated with BSN {Fall 1988-Spring 1991}.
B. Xavier/Charity of New Orleans, Nurse Anesthesia Program Graduated with Master of Science degree in Nurse Anesthesiology. {January 1994 - May 1996}.
C. University of Phoenix. Master is Business Administration Program. {Sept2011-April 2013}

II. Employment Experience

A. Civilian

1. South Mississippi Anesthesia Associates, Hattiesburg, Mississippi {Jun96-Jul98}
   a. Staff CRNA
2. Hub South Medical Group, Hattiesburg, Mississippi {Jul98-Dec99}
   a. Staff CRNA {Jul98-Jul99}
   b. Chief CRNA {Jul99-Dec99}
3. South Mississippi Anesthesia Associates, Hattiesburg, Mississippi
   a. Chief CRNA {Jan99-Jun02}
4. Pacific Physicians Services, Wesley Medical subunit, Hattiesburg, Mississippi
   a. Staff CRNA {Jun02-Dec06}
5. OMNI Anesthesia Associates, Inc. Fresno, CA
   a. Contract CRNA {Jan07- Dec10}
6. Orr Anesthesia Services, A Professional Nursing Corporation, Clovis, CA
   a. Staff CRNA {Jan11-current}
   b. Hosted "Kilts and Anesthesia 2011", CME conference in Edinburgh, Scotland, August 1st-6th, 2011

B. Military

1. Louisiana Army National Guard {Aug1991- 26Apr2004}
   a. 1060th Medical Detachment Surgical. {Nov97-Jul99} Duties Executive Officer and for all training and equipment for the 1060th. Performed as Commanding Officer for 1060th in Annual Training at Fort Polk, Louisiana in summer of 1998 and 1999. Have served as the Chief Nurse Anesthetist for the Louisiana National Guard since Nov97.
   b. Company C 199th Support Battalion {Jul99-14May2004) Chief Nurse Anesthetist. Train medical and non-medical personnel in soldier skills and medical skills.
2. United States Army Reserve {26Apr2004- current}
   a. Captain {26Apr2004 – 22Jun2004} Staff Nurse Anesthetist. Train medical and non medical personnel in soldier skills and medical skills
   b. Major {22Jun2004 –31Dec2006}
      1.) Staff Nurse Anesthetist. Train medical and non medical personnel in soldier skills and medical skills
      2.) Activated to Iraqi Freedom {26May2005 – 9Sept2005} and sent to Heidelberg, Germany as a staff nurse anesthetist and was acting as Chief Nurse Anesthetist July 2006.
      3.) Chief Nurse of operating room May 2006
   c. Retired Reserves, Retired Major 20 years of service. {Dec06- Current} (Enlisted Service US Navy Reserves and Mississippi Army National Guard, {26Apr1986-11May1991} No breaks in service)

C. Facilities Where Have Privileges

1. Renaissance Surgery Center
   2365 E Fir Ave
   Fresno, CA 93720
   (2018 to current)
2. Fresno Dental Surgery Center
   2828 Fresno St STE 100
   Fresno, CA 93721
   (2008 to current)
3. Eye-Q Vision Center (Out Patient Surgery Center)
   7075 North Sharon Avenue
   Fresno, CA 93720
   (2007 to current)

From:	Bryce Docherty
To:	Olney, Jessica@DCA
Cc:	Wallace, Sarah@DCA; Beth LaBouyer; Bryce Docherty
Subject:	CASA Written Comments: Title 16 - Dental Board of California SB 501 Anesthesia and Sedation
Date:	Monday, February 14, 2022 6:10:37 PM
Attachments:	image003.png DBC.CASA SB 501 Anesthesia and Sedation Regualtions Comments.FINAL2.14.22.pdf
Importance:	High

[EXTERNAL]: [redacted]

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Ms. Olney:

Please find the attached written comments from the California Ambulatory Surgery Association (CASA), regarding Title 16 – Dental Board of California SB 501 Anesthesia and Sedation CCR Section 1017.1 *et seq*.

Please confirm receipt and contact me directly with any questions or need for additional information.

Bryce W.A. Docherty
Founder & CEO
TDG STRATEGIES
1215 K Street, 17th Floor
Sacramento, California 95814
Phone/Text: (916) 769-0573
[redacted]
Web: www.tdgstrategies.com
Pronouns: He/Him/His

February 14, 2022

Jessica Olney
Staff Services Manager I
Dental Board of California
2005 Evergreen Street, Suite 1500
Sacramento, CA 95815

Sent via email to: jessica.olney@dca.ca.gov; sarah.wallace@dca.ca.gov

RE: Senate Bill (SB) 501 Anesthesia and Sedation (CCR, Title 16, Sections 1021, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1043.8.1, 1043.9.1, 1043.9.2, 1044, 1044.1, 1044.2, 1044.3, 1044.4, 1044.5, 1070.8)

Dear Ms. Olney:

On behalf of the California Ambulatory Surgery Association (CASA), and our over 400 members, we appreciate the opportunity to provide our written comments and insights on the proposed regulation referenced above to implement SB 501 (Glazer) – Chapter 929, Statues of 2018.

We are the statewide association of Ambulatory Surgery Centers (ASCs) and our members champion the advancement of ambulatory surgery technology and promote the efficient, safe and effective utilization of resources that benefit our patients. CASA members are leaders in reducing costs to the health care system as we ensure patients are treated safely in outpatient settings instead of other costly alternatives.

California has become a national leader in expanding health care coverage to almost all residents but access to that care and the cost of providing it remains a monumental challenge. In fact, the California Health Care Foundation (CHCF) has released their second annual California Health Policy Survey and found that more than 8 out of 10 or (84) percent California residents rated making health care more affordable as either "extremely important" or "very important." CASA members provide significant savings to the California health care system. For example, UC Berkeley research has shown that every procedure performed in an ASC saves the Medicare program forty (40) percent and saves Medicare beneficiaries fifty-sixty (50-60) percent in their co-payments.[1]

Currently there are approximately 64 ASCs in California providing some form of dental services with a small amount of those facilities exclusively providing dental procedures. ASCs are regulated under a variety of state and federal requirements. For example, an ASC can perform procedures on patients if they meet one of three

[1] Fulton, Brent; Kim, Sue. *Study: Medicare Cost Savings Tied to ASCs.*

criteria: 1.) Licensed by the California Department of Public Health (CDPH) as a "surgical clinic" pursuant to Health and Safety Code Section 1204(b)(1); or 2.) Accredited as an "outpatient setting" by one of the five accrediting bodies approved by the Medical Board of California (MBC) pursuant to Health and Safety Coode Section 1248; or 3.) Certified by the Medicare Program as an "ambulatory surgical center." Under these regulatory scenarios it's either CDPH, MBC and/or accrediting bodies, or CMS and/or their contracting entity that can take corrective action against the facility. The Dental Board of California (DBC) has no statutory or regulatory authority to regulate these facilities, regardless of the level of sedation and anesthesia being provided nor the types of dental procedures that are being performed. The only authority the DBC has is over the licensed dentists performing these procedures in these "outpatient" settings.

For a more in-depth analysis of these dental ambulatory surgery centers and the applicability of California Business and Professions Code Section 1646, *et seq*. (21009-001), please see the attached memo from September 10, 2019, to the DBC prepared by Jeanne Vance and Jennifer Nguyen from Salem and Green.

So, as CASA reads the proposed regulations, they appear to miss the mark on the definition of "outpatient" and "outpatient setting." Those definitions only seem to exempt "a treatment facility which is accredited by the Joint Commission on Health Care Organization or licensed by the California Department of Health Care Services as a 'general acute care hospital' as defined in subdivision (a) of Section 1250 of the Health and Safety Code." These regulations also only get it half right with the definition of "outpatient setting" under Article 5.5 Oral Conscience Sedation by referencing Health and Safety Code Section 1248 and 1248.1.

Therefore, we strongly believe that the definitions and exemptions in these regulations need to be specific to an ASC that is accredited, Medicare certified and/or state licensed. Existing California law already provides for these definitions. For example, we would suggest proposing language similar to Business and Professions Code Section 4190(a), which states:

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

So, for these regulations, we'd suggest defining "outpatient setting" that comports with existing law by suggesting the following language:

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

These "outpatient settings" must be exempt from the regulations and any regulatory oversight by the DBC. Otherwise, what the DBC is promulgating will be considered an "underground regulation" by creating barriers to access to care without proper enabling statue authorizing the DBC regulatory oversight of these facilities.

CASA has identified the following necessary changes to these regulations outlined below:

Chapter 2. Dentists: Article 5. General Anesthesia and Moderate Sedation Section 1043. Definitions.

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

Amend to read:

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

Chapter 2. Dentists: Article 5. General Anesthesia and Moderate Sedation Section 1043.3. Onsite Inspections.

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

Amend to read:

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

Chapter 2. Dentists: Article 5.1. Pediatric Minimal Sedation Section 1043.9. Definitions.

(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility which is 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.

Amend to read:

(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility which is a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

Chapter 2. Dentists: Article 5.1. Pediatric Minimal Sedation Section 1043.9.1. Requirements; Standards.

(a) A licensed dentist who desires to administer or order the administration of pediatric minimal sedation on an outpatient basis is not required to apply to the Board for a pediatric minimal sedation permit if they possess another sedation permit from the Board.

Amend to read:

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

Note Business and Professions Code Section 2725(b), which states:

(b) The practice of nursing within the meaning of this chapter means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:

(1) Direct and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures.

(2) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.

Chapter 2. Dentists: Article 5.5. Oral Conscious Section 1044. Definitions.

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

Amend to read:

(a) "Outpatient basis" means a dental office where oral conscious sedation is being provided to dental patients with the exception of a treatment facility which is a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

The following suggestion would require statutory changes that could be included in SB 652 (Bates): Dentistry: Use of Sedation: Training:

Senate Bill (SB) 501 Anesthesia and Sedation Regulations: Page 46, Business and Professions Code Section 1647.2.

Requirements for administration of moderate sedation on
outpatient basis; Requirements for administration to pediatric patients; Applicability [Operative January 1, 2022]
(a) A dentist may administer or order the administration of moderate sedation on an outpatient basis for a dental patient if one of the following
conditions is met:
(1) The dentist possesses a current license in good standing and either holds a valid general anesthesia permit or obtains a moderate sedation permit.
(2) The dentist possesses a current permit under Section 1638 or 1640 and either holds a valid general anesthesia permit or obtains a moderate sedation permit.
(b) A dentist shall obtain a pediatric endorsement on the moderate sedation permit prior to administering moderate sedation to a patient under 13 years of age.
(c)(1) A dentist who orders the administration of moderate sedation shall be physically present in the treatment facility while the patient is sedated ***with the exception of a treatment facility which is a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.***
(2) For patients under 13 years of age, there shall be at least two support personnel in addition to the operating dentist present at all times during the procedure involving moderate sedation. The operating dentist and one personnel member shall maintain 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. The personnel member with current certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management shall be dedicated to monitoring the patient during the procedure involving moderate sedation and may assist with interruptible patient-related tasks of short duration, such as holding an instrument.

Thank you for your consideration. For further questions or need for additional information, please contact CASA Legislative Advocate Bryce Docherty at (916) 769-0573 or [redacted]

Sincerely,

Elizabeth LaBouyer
Executive Director
California Ambulatory Surgery Association
[redacted]

cc: Sarah Wallace, Interim Executive Officer, Dental Board of California
Kimberly Kirchmeyer, Director, California Department of Consumer Affairs
Honorable Jim Wood, D.D.S.

(Attachment)

SALEM & GREEN

A PROFESSIONAL CORPORATION

MEMORANDUM

TO: Dental Board of California

FROM: Jeanne L. Vance, Jennifer V. Nguyen

DATE: September 10, 2019

RE: Dental Ambulatory Surgery Centers – Applicability of California Business and Professions Code Sections 1646, *et seq.* (21009-001)

I. General Anesthesia in "Outpatient Settings"

Under California law, outpatient surgeries requiring general anesthesia may be lawfully rendered at any of the following settings:

- An ambulatory surgical center certified by the Center for Medicare and Medicaid Services ("CMS") to participate in the Medicare program;
- A clinic located on federally-recognized tribal land and conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization;
- A clinic directly conducted, maintained, or operated by the United States;
- A surgical clinic licensed by the California Department of Public Health;
- A health facility licensed as a general acute care hospital;
- An outpatient setting to the extent used by a dentist or physician and surgeon in compliance with the California Dental Practice Act;[1] and
- An outpatient setting that is accredited by an accreditation agency approved by the Medical Board of California.[2]

These alternative settings are mutually exclusive, and an outpatient setting need only meet one of these provisions to furnish anesthesia services to a patient.

II. California Business and Professions Code Section 1646.1(a) Does Not Apply to Services Performed in a Medicare-Certified Ambulatory Surgery Center

The Business and Professions Code specifies that no dentist shall administer or order the administration of general anesthesia on an outpatient basis for dental patients unless the dentist possesses a current license in good standing to practice dentistry in the state and holds a valid general anesthesia permit issued by the Dental Board of California ("DBC").[3]

This provision does not apply to dental ambulatory surgery centers ("Dental ASC") because: (1) if a Dental ASC meets the definition of an "outpatient setting" as defined under the Health and Safety

---

1 The Dental Practice Act is found at Cal. Bus. & Prof. Code § 1600, *et seq.*

2 Cal. Health & Safety Code § 1248.1.

3 Cal. Bus. & Prof. Code § 1646.1(a).

Code, then it is only subject to general anesthesia requirements under same; and (2) Section 1646, *et seq.,* only applies to general anesthesia rendered in a dentist office and not an ambulatory surgery center.

A. A Dental ASC is not subject to the jurisdiction of DBC if it is an outpatient setting subject to general anesthesia requirements under the Health and Safety Code.

If Dental ASC meets the requirements of an "outpatient setting" as defined by the Health and Safety Code, then it is only subject to the requirements for general anesthesia as provided under same, and Section 1646.1(a) of the Business and Professions Code ("Section 1646.1(a)") is inapplicable.

For example, if Dental ASC is licensed as a surgical clinic under Section 1204 of the Health and Safety Code, then the delivery of its services is overseen and regulated by the California Department of Public Health ("CDPH"). The CDPH applies the Medicare regulations applicable to Medicare certified ambulatory surgery centers. Thus, the delivery of general anesthesia at Dental ASC is set forth in the Medicare State Operations Manual. To require Dental ASC to also meet the standards set forth in the Business and Professions Code would result in a conflict of law that subjects ambulatory surgery centers to inconsistent requirements regarding the provision of anesthesia services.

Of note, one of the outpatient settings in which anesthesia can be lawfully rendered under Section 1248.1 of the Health and Safety Code is an outpatient setting that is used by a dentist or physician and surgeon in compliance with Section 1646, *et seq.,* of the California Business and Professions Code. To the extent that Dental ASC is an outpatient setting used by a dentist or physician and surgeon, it is not required to comply with Section 1646, *et seq*., because each of the outpatient settings listed in Section 1248.1 of the Health and Safety Code are alternatives, and Dental ASC need only meet one of the provisions to lawfully render anesthesia services.

B. The Dental Anesthesia Permit Requirements Set Forth in Section 1646.1 Do Not Apply to Services Provided Outside of a Dental Office.

Although the language of Section 1646.1(a) refers to general anesthesia provided on an outpatient basis and does not specify any specific outpatient setting for which the permit is required, other provisions in the Dental Practice Act indicate that the permit requirement is only directed for general anesthesia provided in a dentist office. For example, Section 1646.9 provides that a physician and surgeon licensed by the Medical Board of California may administer general anesthesia ***in the office of a licensed dentist*** for dental patients, without regard to whether the dentist possesses a general anesthesia permit, if the physician and surgeon holds a current license in good standing to practice medicine in the state and holds a general anesthesia permit issued by the DBC.[4] Additionally, Section 1043.1 of Title 16 of the California Code of Regulations states that a licensed dentist does not need a general anesthesia permit if the general anesthesia administered ***in that dentist's office*** is directly administered by a licensed dentist or physician and surgeon who holds a general anesthesia permit.[5]

Given that other provisions in the Dental Practice Act and the Dental Boards Regulations[6] specifically narrow the requirement for a general anesthesia permit to only those services ***furnished in a dentist office***, it would be inconsistent with the law to apply Section 1646.1(a) to other settings such as ambulatory surgery centers.

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4 Cal. Bus. & Prof. Code § 1646.9(a) ("Section 1646.1").
5 16 Cal. Code of Regs. § 1043.1(a)
6 The California Dental Board's regulations are found at 16 Cal. Code of Regs. § 1000 *et seq.*

III. CRNAs May Deliver General Anesthesia at a Medicare-Certified Ambulatory Surgery Center by Dentist's Order without Having a Dental Anesthesia Permit

As discussed above, Section 1646.1(a) of the Business and Professions Code requires that dentists obtain a valid general anesthesia permit from the DBC in order to administer or ***order the administration of general anesthesia*** on an outpatient basis to dental patients.[7] As such, this provision also applies to the use of certified registered nurse anesthetists ("CRNA") to render general anesthesia services at the order of a dentist or physician and surgeon.

That Section 1646.1(a) only applies to the dentist office setting is reinforced by other provisions in the Business and Professions Code governing the use of a CRNA licensee. For example, under the Business and Professions Code, the use of a CRNA to provide anesthesia services in an acute care facility need only be approved by the acute care facility and at the discretion of the physician or dentist.[8] The dentist is only required to hold a general anesthesia permit as required by Business and Professions Code Section 1646.1(a) if the general anesthetic agent is administered ***in a dental office***.[9]

There is nothing to the contrary in the Medicare State Operations Manual that would indicate that Section 1646.1(a) requires a dentist or physician and surgeon to write orders for general anesthesia services delivered by a CRNA ***in an ambulatory surgical center, surgical clinic, or other outpatient setting***. Under the Medicare State Operations Manual, anesthetics may be administered by (1) a qualified anesthesiologist, or (2) a physician qualified to administer anesthesia, a CRNA, or an anesthesiologist's assistant, or a supervised trainee in an approved educational program.[10] A "physician" is defined to include a doctor of medicine or a doctor of dental surgery or of dental medicine.[11]

While the Medicare State Operations Manual requires an ambulatory surgery center to have policies and procedures designed to promote medication administration consistent with acceptable standards of practice, including the requirement that a physician, dentist or other qualified member acting within their scope of practice ***must issue an order*** for all drugs or biologicals administered in the ambulatory surgery center,[12] there is no specified requirement that the order must come from a dentist or a physician who holds a valid general anesthesia permit issued by the DBC.

JVN:dpf

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7 Cal. Bus. & Prof. Code § 1646.1(a)(1).
8 Cal. Bus. & Prof. Code § 2827.
9 Id.
10 State Operations Manual for Medicare, Appendix L, Guidance for Surveyors: Ambulatory Surgical Centers, § 416.42(b).
11 Social Security Act, § 1861(r).
12 State Operations Manual for Medicare, Appendix L, Guidance for Surveyors: Ambulatory Surgical Centers, Interpretive Guidelines: § 416.48(a).

From: McCune, Mary
To: Wallace, Sarah@DCA
Cc: Bruce Whitcher; Pittman-Spencer, Brianna; Olney, Jessica@DCA
Subject: SB 501 Regulations Public Comment
Date: Tuesday, February 15, 2022 11:09:18 AM
Attachments: SB 501 Reg CDA Public Comment Letter.pdf

[EXTERNAL]: [redacted]

WARNING: This message originated from the public internet. Do not open attachments unless you recognize the sender.

Hi Sarah,

Attached please find CDA's public comments on the Board's proposed regulations to promulgate SB 501. Thanks!

Mary McCune (she/her/hers)
Policy Director, California Dental Association
Executive Director, California Dental Association Foundation
CDA | **CDA Foundation**| TDIC | TDIC Insurance Solutions
1201 K Street, 15th Floor, Sacramento, CA 95814
800.232.7645 | **916.554.5359** | 916.342.3609 mobile
[redacted] **cda.org** | **cdafoundation.org**

February 15, 2022

Ms. Sarah Wallace
Interim Executive Officer
Dental Board of California
2005 Evergreen Avenue, Suite 1550
Sacramento, CA 95815
RE: Comments on SB 501 draft Regulations

Dear Ms. Wallace,
The California Dental Association appreciates the opportunity to comment on the proposed regulations to promulgate the pediatric anesthesia requirements set forth in SB 501(Glazer, 2018). CDA respectfully submits the comments below:

1. **Title and fee information missing from the application for pediatric endorsement form.**

We wish to call your attention to page 49 of the draft regulatory package, Form PE-1 (05/2021). We assume this is the application for pediatric endorsement, however, it is titled "Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement." The title of this form appears to be missing as well as the fee information for this application. The form should be corrected to allow for the collection of a fee for the pediatric endorsement for the deep sedation-general anesthesia permit and moderate sedation permit. The case documentation is included in Form PE-1 for both permits.

2. **No criteria are included for board-approved training in pediatric life support and airway management. These criteria for board-approved training in pediatric life support and airway management, consistent with BPC 1601.8, should be developed and added to the draft regulations.**

The draft regulations for permit application and renewal for deep sedation/general anesthesia permits and the moderate sedation permits include language from SB 501 that states: "The operating dentist and at least one of the additional personnel shall maintain current certification in Pediatric Advanced Life Support (PALS) *or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8.*"

The Initial Statement of Reasons (pages 59, 60) states that "(t)he 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 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

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States." The DBC did not consider development of a board-approved course in pediatric advanced life support an airway management, which is included as an alternative to PALS in SB 501.

CDA held stakeholder meetings to develop recommendations for a course that would be more appropriate for dental providers than PALS. PALS includes content most appropriate for medical providers such as pediatricians in the primary care setting, the emergency department or the pediatric hospital ward, not dental facilities. Dental anesthesia specialty associations such as the American Society of Dental Anesthesiology and other experts in the field have developed courses that would meet the requirements of 1608.1.

There is currently no description in the draft regulations of a course or courses that the DBC deems equivalent within the meaning of section 1608.1. The DBC should, therefore, develop regulations that specify the required course content for pediatric advanced life support and airway management, which would include the subject matter of the instruction and requirements for a live, in-person skills practice session, a skills test and a written examination that is appropriate for dental anesthesia and providers and their staff. The alternative courses could be approved in a manner similar to general C.E. courses or mandatory C.E. courses.

3. **The proposed language in 1043(b) that defines "outpatient (facility)" is inconsistent with the definition specified in HSC 1248-1248.1. The draft regulations, Section 1043 "[d]efinitions," should cite the definition of an outpatient setting used in HSC 1248-1248.1, because this includes outpatient facilities, other than dental offices, where dentistry is performed.**

The draft regulations, section 1043 (b), page 4, define "outpatient" as a patient treatment facility, which is not accredited by the Joint Commission or licensed by the California Department of Health Care Services as a general acute care hospital as defined in subdivision (a) of Section 1250 of the HSC. Section 1250 defines an acute care facility as one in which patients are admitted for a 24-hour stay or longer, as opposed to an "outpatient facility" where patients are admitted for less than 24 hours.

The proposed draft regulations on page 18, Article 5.5 "Oral Conscious Sedation" 1044, Definitions, (a), include the HSC definition of an outpatient setting from Section 1248 and 1248.1. For clarity, this definition should also be included on page 4, Article 5, General Anesthesia, and Moderate Sedation. 1043, "Definitions" (b):

"(b) "Outpatient basis" means "outpatient setting" as used in Health and Safety Code Sections 1248 and 1248.1 and means all settings where deep sedation/general anesthesia , moderate sedation, of oral sedation are 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 Care Services as "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

Section 1248.1 is included below for reference:

HSC 1248.1 describes outpatient facilities that may operate in California:

(a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.
(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.
(c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.
(d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.
(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).
(f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.
(g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.
(h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

4. The DBC should clarify whether a dentist may order the administration of deep sedation/general anesthesia within their scope of practice in an outpatient facility as described in HSC 1248.15 (3).

BPC 1646 restricts dentists from "ordering the administration of deep sedation or general anesthesia on an outpatient basis" unless they hold a deep sedation/general anesthesia permit. The Medical Board of California approves the agencies that accredit outpatient facilities. The minimum accreditation standards are established in HSC 1248.15 (3). This section describes the allowable use of outpatient facilities by dentists and CRNAs.

"(3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code."

We note that the DBC may not be able to determine whether dentists have the authority to order the administration of deep sedation/general anesthesia by a CRNA during the current rulemaking due to pending legislation (SB 889).

5. The DBC should define equivalency standards for training in pediatric moderate sedation for the pediatric endorsement in the draft regulations in the Certification of Training in Moderate Sedation for Patients Under 13 Years of Age (page 48).

BPC 1647.3(d)(1) states in pertinent part that a dentist may apply for a pediatric endorsement for a moderate sedation permit by confirming that they successfully completed a CODA-accredited pediatric residency or *equivalent training in pediatric moderate sedation, as determined by the DBC*. CODA pediatric residency accreditation standards (page 28) specify that students **must** complete a minimum of 50 patient encounters in which sedative agents other than nitrous oxide (but may include nitrous oxide in combination with other agents) are used. The agents may be administered by any route. Of the 50 patient encounters, each student/resident **must** function as operator in a minimum of 25 sedation cases. Of the remaining sedation cases (those not performed as the primary operator), each student/resident **must** gain clinical experience, which can be in a variety of activities or settings, including individual or functional group monitoring and human simulation.

SB 501 requires the applicant for a pediatric endorsement to the moderate sedation permit to complete 20 cases at time of application and at each renewal. The DBC should consider the completion of the 20 cases as essentially equivalent to the CODA accreditation standard and therefore sufficient to establish eligibility for the pediatric endorsement for applicants who have not completed a CODA-accredited pediatric dental residency.

6. The certification of training for the pediatric endorsement for the moderate sedation permit appears to be missing from Form PE-1 (page 49). This information should be added to Form PE-1.

Form PE-1 located on page 49 of the regulatory package refers to "[d]ocumentation of deep sedation and general anesthesia or moderate sedation case for pediatric endorsement," which is apparently the application for the pediatric endorsement. We have recommended that this form be retitled, and this form appears to be missing a certification of training where the applicant certifies they have completed the training specified by BPC 1647.2 for moderate sedation of patients under age 13.

7. Certification of training form for application for the use of oral conscious sedation for adult patients is missing in draft regulations.

The certification of training form (page 67) appears to be missing from the adult oral conscious sedation draft regulations. Certification of training should be added to the OCS for adults application, Form OCS-C. Business and Professions Code 1647.20 specifies the registration and requirements for certain dentists to administer oral conscious sedation to adult patients. The form should be similar to the Certification of Training for Pediatric Minimal Sedation on page 66, draft SB 501 regulations. Forms OCS-2 and OCS -3 (11/20) previously used for this permit application could be updated and inserted after page 67 of the draft regulations to replace form OCS-C. Forms OCS-2 and OCS-3 include the required certification of training as specified in SB 501.

CDA appreciates the opportunity to provide comments regarding the DBC's proposed regulations on implementing the pediatric dental anesthesia requirements set forth from SB 501. Please contact me at 916.554.5359 or by email at mary.mccune@cda.org if you have any questions or concerns.

Sincerely,

Mary McCune
Director of Policy
California Dental Association

From: Jeremy Pierson
To: Olney, Jessica@DCA
Cc: Wallace, Sarah@DCA
Subject: Request for wording clarification in regulations for SB 501
Date: Tuesday, February 15, 2022 3:24:42 PM
Attachments: SB 501-Coalition Letter.pdf

[EXTERNAL]: [redacted]

WARNING: This message originated from the public internet. Do not open attachments unless you recognize the sender.

Hello Ms. Olney & Ms. Wallace,

Please find the attached letter to be entered into the public discussion and record on the regulations being written for SB 501.

We have put a lot of time and effort into providing you with wording that will clarify some of the ambiguity in the regulations as they are currently written. We hope these changes will be useful to you as you make the necessary changes to the regulations so all constituents will be benefited by the work the Dental Board is doing.

Please respond to this email to ensure that you have received it.

Thank you,

Jeremy

FRESNO DENTAL SURGERY CENTER

INDIO SURGERY CENTER

Bay Area Dental Surgery Center

ALL KIDS DENTAL SURGERY CENTER

BlueCloud Pediatric Surgery Centers

Salida Surgery Center

Sarah Wallace, Interim Executive Officer
Jessica Olney, Staff Services Manager I
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

Re: SB 501 – Clarification of differentiation between a dental office and an Ambulatory Surgery Center (ASC)

SUMMARY OF REQUEST

The Dental Board of California is drafting regulations to implement SB501. The most recent draft does not clearly distinguish dental offices from ambulatory surgical centers. The safety standards that would be imposed by the application of new credentialing standards on ASCs are not necessary due to the high legal standards already in place for the provision of anesthesia in an ASC setting. Unduly restricting the persons who can delivery anesthesia would also exacerbate a very difficult staffing situation in ASCs. The staffing shortages among California healthcare providers are well-known and implementing these restrictions on a provider type that provides high quality care in California would simply mean that many of them could not continue to provide services in California.

The operative language is currently contained in Section 1043(b), which states:

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

In order to properly distinguish ambulatory surgical centers in the wording of this regulation, the following language in **blue** should be added to the current proposed language in Section 1043(b):

(b) For purposes of this article, "outpatient" means a patient treated in a treatment facility that is not: accredited **as a general acute care hospital or ambulatory surgery center** by the Joint Commission on Health Care Organizations **or the Accreditation Association of Ambulatory Health Care; or certified as a general acute care hospital or an ambulatory surgery center by the Centers for Medicare & Medicaid Services**; or licensed as a "general acute care hospital" as defined in subdivision (a) or Section 1250 of the Health & Safety Code.

Please also see additional proposed wording modifications to the Dental Board-proposed amendments attached to this letter.

GENERAL BACKGROUND

Ambulatory surgical centers "ASCs" are facilities where treatment that does not require hospital admission is performed. In California there are several ASCs that have opened their fully equipped operating rooms for dental treatment, and these ASCs are able to prevent hospital operating rooms and Emergency Rooms from becoming overwhelmed by acute dental cases. If ASCs are not available to general dentists as a place to refer their patients who cannot have their dental treatment completed in a regular dental office, hospital emergency rooms could soon be overwhelmed by acute cases of dental disease. Further, ASCs in California play a critical role in dental treatment of children, especially those in the minority populations. In California, nearly 30,000 children per year receive pediatric dental care in ASCs. The majority are from lower socioeconomic families, in extreme pain, and generally have had very limited access to dental care. Without ASCs, children will be unnecessarily prescribed pain medication for their dental trauma and emergency departments will likely be overwhelmed with dental cases that they cannot treat. In addition, ASCs provide an affordable option for developmentally disabled patients who cannot have treatment completed in a normal dental office.

Section 1601.7(4) of the Business and Professions Code, directs the Office of Oral Health in the State Department of Public Health to provide to the Legislature a report and analysis "of disparities to access of needed dental anesthesia care by racial or ethnic background, insurance status, geographic area, or other relevant categories." If you analyze this report, it is clear that access to care for children living in the lowest socioeconomic levels is a significant problem in California, and much more so for kids with Special Needs, severe dental disease, and severe phobias who cannot have treatment completed in a regular dental office. By failing to clearly define ASCs in the wording of these regulations, the minority population and lower socioeconomic families will be negatively affected, and the disparities in dental treatment options for the poor and minority families will continue to grow.

ASCs are licensed by the California Department of Public Health under Health and Safety Code §1248 to provide general anesthesia. A normal dental office does not possess such a license. Further, section 1248(3)(c) establishes public and private "accreditation agencies" to provide accreditation to Outpatient settings, agencies such as The Joint Commission and the Accreditation Association for Ambulatory Heath Care (AAAHC). **ASCs must have this accreditation as stated in 1248.1(g). These strict regulations go far and above and beyond the safety standards required for a dental office in SB 501.**

Sincerely,

Alan Vallarine

Alan Vallarine, DDS
Owner & Dental Director
Fresno Dental Surgery Center

Larry Church

Larry Church, DDS
Owner
Indio Surgery Center

PK Patel

Pankaj Patel, DMD
Owner & Medical Director
Salida Surgery Center
Bay Area Dental Surgery Center

Devin Larson

Devin Larson
CEO
Blue Cloud Pediatric Surgery Centers

Marcus Kasper

Marcus Kasper
Owner & Administrator
All Kids Dental Surgery Center

Dental Ambulatory Surgery Center Proposed Amendments to AB 501 Proposed Regulations

Wording removals are in ~~RED~~ and wording additions are in BLUE

1043. Definitions

(b) For purposes of this article, "outpatient" means a patient treated in a treatment facility that is not: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or the Accreditation Association of Ambulatory Health Care; or certified as a general acute care hospital or an ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed as a "general acute care hospital" as defined in subdivision (a) or Section 1250 of the Health & Safety Code.

1043.3. Onsite Inspections

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

1043.9 Definitions.

(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility that is: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or the Accreditation Association of Ambulatory Health Care; or certified as a general acute care hospital or ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed by the California Department of ~~Health Services~~ Public Health as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

1044. Definitions.

(a) "Outpatient basis" means "outpatient setting" as used in Health & Safety Code Sections 1248 and 1248.1 and means all settings where oral conscious sedation is being provided to dental patients with the exception of a treatment facility that is: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or American Association of Ambulatory Health Care; or certified as a general acute care hospital or ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed by the California Department of ~~Health Services~~ Public Health as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

From: Jeanne L. Vance
To: Olney, Jessica@DCA; Wallace, Sarah@DCA
Subject: Proposed Rulemaking Package; SB 501 (Anesthesia & Sedation)
Date: Tuesday, February 15, 2022 3:57:29 PM
Attachments: Letter to Dental Board of CA.pdf
Proposed Regulations - Amendments (AB501).pdf
AAOS Article.pdf
ASC Review Article.pdf

[EXTERNAL]: [redacted]

WARNING: This message originated from the public internet. Do not open attachments unless you recognize the sender.

Please find attached comments on this Proposed Rulemaking Package. Due to the size of the attachments, I am sending one of the attachments as a second email. Would you kindly confirm receipt of this email? Thank you so much.

Best regards,

Jeanne

Jeanne L. Vance
Shareholder

[redacted]
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MERITAS LAW FIRMS WORLDWIDE

Jeanne Vance
916-558-6102 DIRECT
jvance@weintraub.com

February 15, 2022

VIA E-MAIL: Jessica.Olney@dca.ca.gov and Sarah.Wallace@dca.ca.gov

Jessica Olney
Staff Services Manager I

Sarah Wallace
Interim Executive Officer
Dental Board of California

Dear Ms. Olney and Ms. Wallace:

This firm represents ambulatory surgery centers and other healthcare providers in California. We ask the Dental Board to modify its proposed regulations in connection with SB 501 (anesthesia standards) to distinguish between the standards it is attempting to apply to dental offices and ambulatory surgery centers, which already have high legal quality standards relating to the delivery of surgery and anesthesia services and which are the subject of oversight by the Centers for Medicare & Medicaid Services and accrediting bodies very similar to the standards applied to general acute care hospitals.

I do recognize that the legislation was intended to raise the standards for the administration of anesthesia in dental offices, which were largely unregulated before the implementation of SB 501. However, the application of these new standards to a separate provider type that already is highly-regulated and considered to be a safe, less-expensive alternative to care received in a hospital. See: Ambulatory Surgery Centers Versus Hospital-based Outpatient Departments: What's the Difference? (aaos.org) ("ASCs have been shown to have greater efficiency with no differences in complication rates compared to HOPDs.) See also: Benchmarking study of 1,000,000 surgeries in ASCs demonstrates minimal surgical site infections, emergency department visits and readmission rates (beckersasc.com)

We are attaching for your use a copy of the instructions that the Centers for Medicare & Medicaid Services gives to its surveyors, which include the accrediting bodies, on how to apply the Medicare standards that apply to Medicare-certified ambulatory surgery centers, are 138 pages. A large percentage of the 138 pages are devoted to different items related to the delivery of anesthesia. Each ASC is measured by these standards when they become Medicare-

certified by either an accrediting body such as the Joint Commission or the American Association of Ambulatory Health Care or the federal Centers for Medicare & Medicaid Services.

The standards that apply to the delivery of anesthesia in these settings are clear:

1. California Health & Safety Code Sections 1248 and 1248.1 provide that they may lawfully administer anesthesia to patients so long as the Medicare/accreditation standards are complied with; and
2. A certified registered nurse anesthetist may lawfully delivery anesthesia in an ambulatory surgery center in California without supervision by another practitioner. See 42 CFR 416.42(c); California Anesthesiologists v. Brown, 204 Cal. App. 45th 390 (2009). This case upheld an "opt out" of physician supervision for CRNA services in California made by Governor Schwarzenegger in California as consistent with state law and in the best interest of California to do so, after having consulted with the Nursing Board and the Medical Board of California.

In addition, both the accrediting bodies and the Centers for Medicare & Medicaid Services are highly sophisticated in the review and regulation of surgical anesthesia.

Application of minimum standards for the delivery of anesthesia intended for dental offices to the highly sophisticated operations of an ambulatory surgery center would run contra the success of ASCs, which have provided a less expensive alternative to hospital care with a similar surgical outcome.

Please amend the proposed regulations with the attached amendments to clarify the standards of SB 501.

Very truly yours,

weintraub | tobin

Jeanne L. Vance

Jeanne Vance
JLV/dvg

Attachments: Proposed Amendments
ASC Survey Standards
ASC Articles

Pediatric Dental Ambulatory Surgery Center Proposed Amendments to AB 501 Proposed Regulations

1043. Definitions

(b) For purposes of this article, "outpatient" means a patient treated in a treatment facility that is not: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or the Accreditation Association of Ambulatory Health Care; or certified as a general acute care hospital or an ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed as a "general acute care hospital" as defined in subdivision (a) or Section 1250 of the Health & Safety Code.

1043.3. Onsite Inspections

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

1043.9 Definitions.

(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility that is: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or the Accreditation Association of Ambulatory Health Care; or certified as a general acute care hospital or ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed by the California Department ~~of Health Services~~of Public Health as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

1044. Definitions.

(a) "Outpatient basis" means "outpatient setting" as used in Health & Safety Code Sections 1248 and 1248.1 and means all settings where oral conscious sedation is being provided to dental patients with the exception of a treatment facility that is: accredited as a general acute care hospital or ambulatory surgery center by the Joint Commission on Health Care Organizations or American Association of Ambulatory Health Care; or certified as a general acute care hospital or ambulatory surgery center by the Centers for Medicare & Medicaid Services; or licensed by the California Department of ~~Health Services~~Public Health as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

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Published 9/1/2019 | Miho J. Tanaka, MD
Practice Management

Ambulatory Surgery Centers Versus Hospital-based Outpatient Departments: What's the Difference?

When performing outpatient procedures, many orthopaedic surgeons operate in either an ambulatory surgery center (ASC) or a hospital-based outpatient department (HOPD). Although some of the workflows and services offered may appear similar between the two, the background operations are substantially different from business and regulatory perspectives.

An HOPD is owned by and typically attached to a hospital, whereas an ASC is considered a standalone facility. However, the difference between an ASC and HOPD specifically refers to the regulations that apply to the center; therefore, a "freestanding" surgery center can still be classified as an HOPD if it is within a 35-mile radius of the hospital and falls under the same financial and administrative contracts. Similarly, a facility can be operated by a hospital and still maintain ASC status if it is an independent entity financially and administratively with its own Medicare agreement. Furthermore, ASCs must comply with the ASC Covered Procedures List, which is aimed at ensuring that procedures with the appropriate level of risk are performed in these freestanding centers.

Cost differences

The regulations and conditions that differentiate ASCs and HOPDs are primarily reflected in cost. Payment rates for the same procedures are lower in ASCs than in HOPDs. Procedures performed in ASCs are reported to cost Medicare 53 percent of the amount paid to HOPDs. According to current data from Medicare's Procedure Price Lookup tool, Medicare payments for knee arthroscopy are $1,005 to ASCs versus $2,098 to HOPDs, with similar differentials in procedures such as knee arthroplasty ($5,914 versus $9,349,

respectively) and open reduction internal fixation (ORIF) of a lateral malleolus fracture ($2,854 versus $4,559, respectively).

The cost differences can have significant effects on the healthcare system. The Center on Health Care Markets and Consumer Welfare at the University of California, Berkeley reported that in 2011, procedures performed in ASCs saved the Medicare program $2.3 billion, with an estimated potential savings of $57.6 billion over the next 10 years. The cost savings also may impact patients in terms of lower copayments and potentially even lower commercial insurance rates. Medicare data show that out-of-pocket costs for patients are also lower for some orthopaedic procedures such as knee arthroscopy ($251 at ASCs versus $524 at HOPDs) and ankle ORIF ($713 versus $1,139, respectively). When combined with the shift toward value-based care, this could contribute to ASCs capturing a greater proportion of the market.

The cost differential between HOPDs and ASCs is partially due to the way payment rates were updated for inflation over time. HOPD payment rates were updated based on the hospital market basket, which is a fixed weight index of costs or services at a later time and can be more predictable, as it is based on factors directly related to the cost of providing medical care. ASC payment updates, in contrast, are subject to the Consumer Price Index for All Urban Consumers, which measures the rising costs of all goods, which are rising more slowly than the cost of medical care.

Advantages of an ASC

ASCs have been shown to have greater efficiency with no differences in complication rates compared to HOPDs. A narrower scope of procedures performed in the ASC setting allows for more specialized care and high patient satisfaction due to smaller and more personalized teams. Selection of technology and scheduling preferences can be more tailored to subspecialties and can place ASCs at an advantage from an operational perspective compared to the HOPD setting. In some ASCs, the option for physician ownership leads to increased autonomy and incentivization, which can translate into increased quality of care due to the effect of direct accountability and alignment of goals between the physician and the surgery center. Physicians who have ownership in an ASC may be more motivated to change or comply with cost-saving or quality-improvement measures that would increase the value of care.

Advantages of an HOPD

The downsides of physician ownership, however, are the financial risks and losses of investment that physicians or owners can sustain. The potential for conflicts of interest in

providing care at a facility where the surgeon can profit financially has been raised as well. However, the converse is true, as many hospitals now have employed physician models to include orthopaedic surgeons.

Some ASCs have therefore chosen to convert to HOPD centers. This may result in loss of physician ownership. In that model, a center must operate under the hospital's regulations and administrative decisions. For physicians, HOPDs allow for more predictable payments for surgical care provided. However, payments may be less than what they could earn in ASCs where they have ownership. In the setting of the current reimbursement gap, HOPDs can have the advantages of higher reimbursement rates and lower costs.

Current trends

Over the past 30 years, the role and number of ASCs have grown considerably, with many orthopaedic procedures increasingly transitioning to the ASC setting. Despite their popularity, growth has slowed recently, with some ASCs choosing to convert to HOPDs to minimize the risks described herein and others terminating their participation in the Medicare program due to the reimbursement gap.

As a result of the transitions, solutions such as comanagement agreements have been developed to allow physicians some leadership in the management of HOPDs without the financial risks associated with ownership of ASCs.

Current efforts to equalize payments between ASCs and HOPDs, along with the addition of several key procedures to the ASC Covered Procedures List, will likely impact the ASC and HOPD market. The changes, as well as a shift toward value-based care, will play important roles in the future of systems that support outpatient orthopaedic procedures.

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ASC Turnarounds: Ideas to Improve Performance

Benchmarking study of 1,000,000 surgeries in ASCs demonstrates minimal surgical site infections, emergency department visits and readmission rates

Since two physicians opened the first modern day surgery center in 1970 in Arizona as a high quality, lower cost alternative to inpatient hospital surgery care, Ambulatory Surgery Centers (ASCs) have transformed the surgical landscape.

Delivering exceptional outcomes and exceedingly high patient satisfaction scores at substantially lower costs, ASCs are arguably one of the greatest values in medicine. Comparative data involving over 1,000,000 surgeries performed in ASCs in 2015 – 2016 from the California Ambulatory Surgery Association (CASA) indicate an ASC post-operative surgical site infection rate six times lower than hospital outpatient surgery departments (HOPD). CASA's benchmarking reports on fundamental quality indicators including infection rates, emergency room visits and readmissions provide increased transparency to patients seeking surgical services.

California, the nation's most populous state, has embraced the ASC, and now is home to more than 760 facilities that are known for pioneering new surgical methods, efficient reimbursement strategies, excellent outcomes, and exceptional patient care[1]. Championing the success and growth of ASCs in the state is CASA. Founded in 1988, CASA is recognized as a leader in the outpatient surgery educational field, providing outcome data, operational comparisons, benchmarking and best practices to ASC managers, healthcare professionals, regulators and the public.

California Benchmarking study of over 1,000,000 surgery cases report an ASC surgical site infection rate six (6) times lower than hospital outpatient departments.

In this report, we will review CASA's benchmarking results and compare them with similar HOPD data. We will also review the medical benefits available to patients who select an ASC for their care, examine the cost savings that ASC patients benefit from, and discuss next steps needed to further develop a universal method of benchmarking.

CASA Benchmarking

CASA collected data from 147 participating ASCs throughout California. These ASCs performed 1,041,000 surgical cases in 2015 and 2016. The participating ASCs represent urban and rural regions of California and range in size from centers with fewer than 1,000 to more than 15,000 cases. They include 100% physician owned and managed ASCs, those partnering with regional and national management firms and those affiliated with large healthcare systems. Data is self-reported, and although some data may be reported to state agencies (i.e. major complications requiring readmission), it has otherwise not been independently verified. The CASA Benchmarking Report creates a measurement standard through 12 distinct metrics grouped into two categories, Quality Indicators and Adverse Risk Events. Quality Indicators measure events that an ASC can actively work to control, such as patient burns, falls, medication errors and post-operative complications. Adverse Risk Events focuses on improving patient care and the ASC risk management protocol. These data

Quality Reporting (ASCQR). ASCQR measures Medicare certified ASCs in ten categories. ASCs are required to report patient burns, falls, hospital transfers and hospital admissions to CMS since 2012. CMS utilizes these quality indicators to determine a portion of payment rates to ASCs[2].

Quality Indicators	Adverse Risk Effects
Hospital Transfer/Admission	Return to Surgery for reasons other than bleeding
Post-Operative Wound Infections (Within 30 days of the procedure or 90 days if the procedure involved an implant of any kind)	Excessive Bleeding requiring return to the Operating Room or transfer
Patient Burn	Cardiac or Respiratory Arrest
Patient Fall in the ASC	Medical Device Errors
Medication Error	Wrong Site Surgery
ER Visit within 48 hours of Discharge	Unintentional retained foreign body

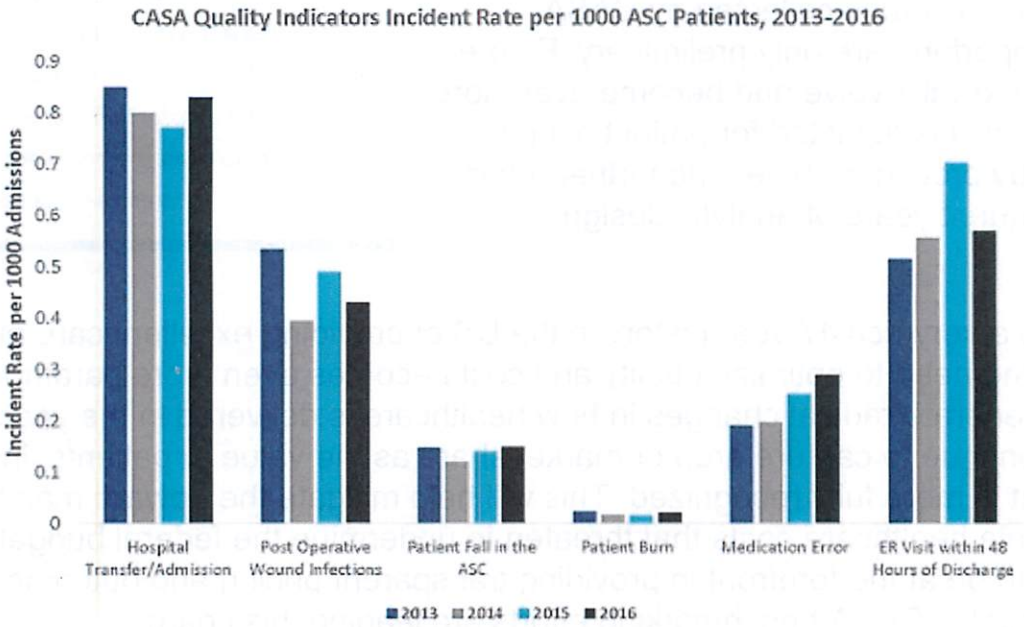
Increased Focus on Key Measurements

Commercial, federal and state payers are increasingly focused on three key outcome measures--hospital transfers or readmissions, emergency room visits within 48 hours of discharge and infection rates—as quality of care markers. The ASC should routinely monitor these outcomes and compare their performance with industry benchmarks.

The post-operative wound infection rates in ASC was .460 per 1,000 surgeries compared to 3.09 per 1,000 in the HOPD. These results may not be entirely comparable as the studies were not adjusted to reflect patient acuity, nonetheless the differences are remarkable and merit additional appropriately controlled research studies.

When compared to some large studies of hospital outpatient departments (HOPD), the ASC demonstrates superior quality of performance. This is evidenced in post-operative wound infection rates, which CASA Benchmarking identified as occurring .460 per 1000 surgeries (412 occurrences per 896,232 patients). An eight state 2014 study of patients receiving outpatient surgery in hospitals, published by the Agency for Healthcare Quality and Research

(AHRQ) found 877 patients out of 280,000 suffered from post-operative treatment for surgical site infection requiring hospitalization. This is an infection rate ratio of 3.09 of every 1,000 or over six and one half times greater than the ASC rate reported by CASA. These results may not be entirely comparable as the studies were not adjusted to reflect patient acuity levels. The differences are nonetheless remarkable and at a minimum, merit additional appropriately designed and controlled research studies. Outcome data comparing the results of identical surgery on patients with similar medical conditions must become transparent to consumers, empowering them to make informed decisions regarding their healthcare options.



Similar to the surgical site infection rate studies on patients receiving outpatient surgery in HOPDs and ASCs, the ASCQR benchmarking program provides a valuable method for measuring performance in the ASC. To generate greater transparency to patients and the public, ASCQR should consider evolving into a universal management tool, comparing patient outcomes focusing on similar surgeries across all providers and facilities. This increased level of transparency will give patients and payers more information creating a much needed consumer driven open market system in healthcare.

...Medicare saved $7 billion between 2007 and 2011 and could potentially save an estimated $12 billion during 2012 – 2016 due to cost savings found through operational efficiencies and clinical performance in ASCs not found in HOPDs.

ASC Cost Savings

Commercial payers recognize the superior outcomes and cost savings provided by the ASC. ASCs save patients and employers an estimated $38 billion per year[3]. Additionally, only 48% of procedures that could be performed in an ASC are actually scheduled there instead of a HOPD, thus suggesting an annual $41 billion opportunity for additional savings2

According to a 2014 report published by the Office of the Inspector General, Medicare saved an estimated $7 billion between 2007 and 2011 and could potentially save an estimated $12 billion during 2012and 2016 due to cost savings found through operational efficiencies and clinical performance in ASCs not found in HOPDs. CASA and other leaders in the ASC industry are at the forefront of promoting transparency in infection rates and other clinical outcome data, patient satisfaction scores and cost, potentially assisting patients consumers and taxpayers save billions of dollars annually[4].

Conclusion

Patient data outcomes collected by CASA, although important, are only preliminary. Future benchmarking will evolve and become ever more meaningful as it is adjusted for patient acuity, separated by procedure type, and further refined with subsequent years of analytic design experience.

CASA and ASCA are at the forefront of encouraging transparency in infection rates and other clinical outcome data, patient satisfaction scores and cost, empowering consumers to make informed decisions regarding their treatment options.

ASCs have a very rich 47 year history in the US of providing excellent care at affordable prices. As the need to optimize quality and cost becomes even more paramount, ASCs are poised to generate radical changes in how healthcare is delivered in the years ahead. The ASC will continue to capture greater market share as the value to patients, insurers, and the government is more fully recognized. This will help mitigate the upward march of unsustainable healthcare costs that threaten to undermine the federal budget. ASCs are well positioned to be at the forefront in providing transparent pricing and outcomes to the American public. CASA benchmarking efforts are leading this charge.

About the Author

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Latest articles on asc news:

Cary Skin Center secures accreditation from Surgical Review Corp.

7 hospitals opening ASCs

From: Jeanne L. Vance
To: Olney, Jessica@DCA; Wallace, Sarah@DCA
Subject: SB 501 Notice of Proposed Action Comment Letter Part 2
Date: Tuesday, February 15, 2022 4:03:56 PM
Attachments: CMS ASC Standards - SOM Excerpt.pdf

[EXTERNAL]: [redacted]

WARNING: This message originated from the public internet. Do not open attachments unless you recognize the sender.

As I indicated in my immediately preceding email, I am attaching the last attachment to my comment letter. Would you kindly confirm receipt?

Thank you so much.

Best regards,

Jeanne

Jeanne L. Vance
Shareholder

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State Operations Manual
Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

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(Rev. 200, 02-21-20)

§416.54 Condition for Coverage: Emergency Preparedness - refer to Appendix Z for tags

Ambulatory Surgical Center Survey Protocol

Introduction

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

Ambulatory Surgical Centers (ASCs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions for Coverage (CfC) in order to receive Medicare/Medicaid payment. The goal of an ambulatory surgical center (ASC) survey is to determine if the ASC is in compliance with the definition of an ASC, ASC general conditions and requirements, and the conditions for coverage (CfCs) at 42 CFR 416 Subparts A through C.

Certification of ASC compliance with the regulatory requirements is accomplished through observations, interviews, and document/record reviews. The survey process focuses on an ASC's delivery of patient care, including its organizational functions and processes for the provision of care. The ASC survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that patients receive safe, quality care, and services.

Regulatory and Policy References

- The Medicare definition of an ASC is found at 42 CFR 416.2 Subpart A.
- General conditions and requirements for Medicare-participating ASCs are found at 42 CFR 416 Subpart B
- The CfCs for ASCs are located at 42 CFR 416 Subpart C.
- Survey authority and compliance regulations can be found at 42 CFR 416 Subpart B and at 42 CFR Part 488 Subpart A.
- Should an individual or entity (ASC) refuse to allow immediate access upon reasonable request to either a State Agency (SA) or CMS surveyor, the Department of Health and Human Services Office of Inspector General (OIG) may exclude the ASC from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. If a surveyor intends to make a request for immediate access with the threat of possible exclusion for non-compliance, the SA must first contact the CMS Regional Office, which must then contact the OIG Administrative and Civil Remedies Branch at 202-619-1306.
- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.

All ASC surveys are unannounced. Do not provide the ASC with advance notice of the survey.

Tasks in the Survey Protocol

The tasks included in a survey protocol for an ASC are:

Task 1 Off-Site Survey Preparation;
Task 2 Entrance Activities;
Task 3 Information Gathering/Investigation;
Task 4 Preliminary Decision-Making and Analysis of Findings;
Task 5 Exit Conference; and
Task 6 Post-Survey Activities.

Task 1 – Off-Site Preparation

General Objectives

The objectives of this task are to determine the size and composition of the survey team and to analyze information about the provider/supplier in order to identify areas of potential focus during the survey. Review of information about the ASC allows the SA (or RO for Federal teams) to develop a preliminary survey plan.

A full or standard survey will be conducted if the purpose of the survey is for initial certification, recertification, or validation of an accreditation organization survey. Surveys in response to a complaint or multiple complaints, or as a revisit to see if a previously cited problem has been corrected, will be focused on the CfCs related to the complaint or on the CfC for which deficiencies were previously identified. This does not preclude the scope of a complaint or revisit survey being expanded, if surveyors observe deficient practices related to other CfCs while on site. (See State Operations Manual, §§5100.1 and 5200.1.)

Types of Surveys

Standard or Full surveys: Initial certification, recertification, and representative sample validation surveys require assessment of the ASC's compliance with all Conditions for Coverage, including the Life Safety Code standards.

- Initial surveys are conducted when an ASC first seeks to participate in the Medicare program.

- Recertification surveys are required to reconfirm at periodic intervals the ASC's ongoing compliance.

- Representative sample validation surveys are conducted to support CMS' oversight of national accreditation organizations (AO) whose ASC programs have been recognized by CMS as suitable for deeming an accredited ASC as meeting the Medicare CfCs. CMS selects the ASCs for this type of validation survey, and

the SA must complete its survey no later than 60 days after the AO's survey. Although the primary purpose of the survey is to validate the AO's oversight, if substantial noncompliance is found by the SA and the RO concurs, the RO initiates appropriate enforcement action. SAs may only survey a deemed ASC when authorized to do so by the CMS Regional Office.

Complaint, Substantial Allegation Validation, or On-site Revisit Surveys: Generally, these types of survey are more narrowly focused than a full standard survey.

- A complaint is an allegation of noncompliance with Medicare health and safety standards. The purpose of a complaint survey is to determine the validity of the allegation and assess the current compliance of the ASC with those CfCs that are relevant to the substance of the allegation that triggered the survey.

- The purpose of the on-site revisit survey is to determine the ASC's current compliance with CfC requirements that the ASC was previously cited for noncompliance.

- The second type of validation survey is the substantial allegation validation. A complaint that alleges substantial noncompliance on the part of a deemed ASC with the Medicare health and safety standards may result in RO direction to the SA to conduct a substantial allegation validation survey. The SA uses the same methodology as for a complaint survey of a non-deemed ASC. The CMS Regional Office must authorize the State Survey Agency to conduct a substantial allegation validation survey and will specify the CfCs to be assessed.

Generally, complaints received by the SA or CMS concern specific cases or incidents that occurred in the past. However, CMS evaluates ASCs only for their current compliance or noncompliance at the time of the survey. Nevertheless, if an investigation of a complaint substantiates a violation in the past of one or more of the CfC requirements, and there is no evidence that the ASC subsequently implemented effective corrective action, then the findings substantiating the violation are documented on the Form CMS- 2567, Statement of Deficiencies and Plan of Correction as evidence of current noncompliance. On the other hand, if an allegation of a violation is substantiated, but the ASC subsequently implemented effective corrective action and the survey reveals no current noncompliant practices, then the ASC is in current compliance and is not cited for a deficiency based on the past noncompliance.

A revisit survey will focus on assessing the ASC's current compliance with the CfCs where deficiencies were cited on the previous survey. The SA must receive an acceptable plan of correction from the ASC before it conducts a revisit survey.

Survey Team Size and Composition

The SA (or the CMS RO for Federal teams) decides the composition and size of the team. In general, a survey team for a standard, i.e., full, survey should include two health standards surveyors and one Life Safety Code (LSC) surveyor, who are on-site for 2

days, but individual circumstances may call for a smaller or larger team, or a shorter or longer period of time on-site. The following factors are considered when determining survey team size and the scheduled length of the survey:

- Size of the ASC, based on its number of operating or procedure rooms (ORs), hours of operation, and/or available information about its average monthly volume of cases;

- Complexity of services offered, e.g., a single type of surgical service, such as eye surgery, or multiple types, such as eye surgery, orthopedic surgery, endoscopies and gynecological procedures;

- Whether the ASC has an historical pattern of serious deficiencies or complaints; and

- Whether new surveyors are to accompany the team as part of their training.

For a complaint or on-site revisit survey, only one surveyor will usually be needed and should be chosen based on their knowledge of the CfC(s) that will be reviewed during the survey.

The ASC surveyors must have the necessary training and experience to conduct a survey. Completion of the Principles of Documentation Training Course is required. Completion of the Basic Ambulatory Surgery Survey Course is required for all health standards surveyors, unless such training has not been offered by CMS in the previous 2 years. All Life Safety Code (LSC) surveys must be conducted by surveyors who have completed the Basic LSC Surveyor Course. All ASC survey teams must include at least one RN with hospital or ASC survey experience who has the expertise needed to determine if the facility is in compliance with the Conditions for Coverage. New surveyors may accompany the team prior to completing the required training.

Team Coordinator

The SA (or the RO) usually designates a Team Coordinator when the survey team consists of more than one surveyor. The Team Coordinator will be responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol. Responsibilities of the Team Coordinator include:

- Acting as spokesperson to the ASC for the team;

- Conducting the entrance and exit conferences,

- Providing other on-going feedback, as appropriate, to ASC leadership on the status of the survey.

- Assigning team members specific survey tasks;

- Facilitating time management;

- Encouraging ongoing communication among team members;

- Evaluating team progress in completing the survey and coordinating team meetings; and

- Coordinating the preparation of the Form CMS-2567, Statement of Deficiencies and Plan of Correction, as well as all other reports/documentation required by CMS.

Assembling Background Information

Surveyors must prepare for the survey offsite, in order to make efficient use of the time onsite at the ASC. If the survey involves more than one surveyor, the Team Coordinator will arrange an offsite preparation meeting. If necessary, this meeting may be by conference call rather than in person. The type of background material to be gathered from the SA's files and/or CMS data bases includes:

- Basic characteristics of the ASC, including the facility's ownership, hours of operation, size, and types of surgical services offered. The most recent Form CMS-377 "Ambulatory Surgical Center Request for Initial Certification or Update of Certification Information in the Medicare Program", shows what the ASC indicates are the services it offers, but this form may be out of date. Other sources of information may include the SA's licensure file;

- Any additional information publicly available about the ASC, e.g., from its Web site, media reports, etc.;

- Any available information on the physical layout of the ASC;

- Whether any Life Safety Code waivers have been issued and are still in effect;

- Survey history and results of previous Federal and State surveys. In the case of a complaint survey, information on whether there were similar complaints investigated in the past; and

- Directions to the ASC.

During the meeting, the team discusses:

- Any significant information identified from the background information assembled;

- Whether there are CfCs requiring particular attention:
    - In the case of a complaint survey, the SA or the RO (in the case of a deemed ASC) identifies in advance of the onsite investigation which CfCs will be surveyed for compliance;
    - In the case of an on-site revisit survey, surveyors will focus on the ASC's current compliance with those CfCs where deficiencies were cited on the most recent Form CMS-2567. Surveyors also review the ASC's plan of correction and will look for evidence while onsite that the plan was implemented. (However, surveyors may not assume that implementation of the plan always means that the ASC is in substantial compliance with the CfC. It is possible that a plan of correction may be implemented, but is not sufficient to bring the ASC into compliance.);
- Preliminary team member assignments;
- Any questions the team has about how they will evaluate the CfCs;
- Date, location, and time team members will meet to enter the facility;
- When daily team meetings will take place if needed; and
- The anticipated date and time of the Exit Conference.

For surveys involving only one surveyor, that surveyor also needs to gather background information and plan the strategy for the survey prior to arriving on-site.

NOTE: Conduct ASC surveys during the ASC's normal business hours. All surveys are unannounced. Do not provide the ASC with advance notice of the survey.

Resources

The following resources are useful to bring on surveys:

- Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers in the SOM;
- Appendix I – Survey Procedures and Interpretive Guidelines for Life Safety Code Surveys in the SOM;
- Appendix Q - Immediate Jeopardy in the SOM;
- Several copies of the regulatory language at 42 CFR 1001.130 regarding the

consequences of failure to permit the survey team access to the facility;

- For deemed accredited facilities, Exhibit 37, Model Letter Announcing Validation Survey of Accredited/Deemed Provider/Supplier, and Exhibit 287, Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey.

Task 2 – Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the ASC staff and obtain the information needed to conduct the survey.

General Procedures

Arrival

The entire survey team should enter the ASC together. Upon arrival, surveyors must present their identification. If the ASC denies entrance to the facility or otherwise tries to limit required survey activities, explain the requirements under 42 CFR 1001.1301 and present a hard copy of the regulatory citation. Explain that failure of the ASC to allow access for an onsite survey could lead to exclusion of the ASC from Medicare.

If surveyors encounter any problems onsite, they should feel free to contact their SA manager or the RO for guidance. For instance, if ASC staff will not let a surveyor into the facility even after they're informed of the possible sanctions that can be imposed for restricting access to their facility, a call to the SA or RO would be appropriate.

Because the survey is unannounced, surveyors should anticipate that in some ASCs, e.g., a small ASC with one physician owner who performs all the ASC's procedures, the ASC's leadership may at the time of entrance by the survey team already be involved in a procedure and unavailable. If there would be a prolonged wait for the ASC's leadership, e.g., a wait exceeding 15 minutes, the team should conduct the entrance conference with available ASC senior staff; a separate brief discussion can be held at a later mutually convenient time with the ASC's leadership.

The Team Coordinator (or the single surveyor for complaint or revisit surveys) will announce to the ASC's Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not onsite or available, the Team Coordinator asks that the Administrator or person in charge be notified that a Federal survey is being conducted. Do not delay the survey because the Administrator is not available.

Entrance Conference

The entrance conference sets the tone for the entire survey. Surveyors must be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief.

During the entrance conference, the Team Coordinator or single surveyor:

- Explains the purpose and scope of the survey (initial certification or recertification; complaint investigation; validation; revisit);

- In the case of a validation survey – either representative sample or substantial allegation (complaint) - of a deemed ASC, presents the letter explaining the survey and has the Administrator sign the authorization for the survey
  (Exhibit 287)

- Briefly describes the survey process;

- Introduces the survey team members, including any additional surveyors who may join the team at a later time, and discusses in general what the surveyors will do and the various documents they may request;

- Clarifies that all areas of the ASC, including the OR(s) or procedure rooms may be surveyed, but emphasizes that the survey team will not interfere with the provision of patient care and will take all standard precautions to avoid any infection control breaches; patients will be asked if they object to having their surgery observed;

- Explains that all interviews will be conducted privately with patients, staff, or visitors, unless requested otherwise by the interviewee;

- Discusses how the facility will provide the surveyors in a timely manner photocopies of material, records, and other information as needed;

- Obtains the names, locations, and telephone numbers of key ASC staff and their responsibilities;

- Discusses the appropriate time, location, and possible attendees of any meetings to be held during the survey; and

- Proposes a preliminary date and time for the exit conference.

During the entrance conference, the Team Coordinator arranges with the ASC Administrator or available administrative supervisory staff in his/her absence, to obtain the following:

- A list of all surgeries scheduled for that day (and the next if a 2-day survey); the list should include each patient's name, age, type of surgical procedure scheduled or performed, and the physician performing the procedure. The Team Coordinator indicates that one surveyor will be following the progression of at least one patient from initial registration through to discharge from the ASC (or at least through the initial period in the recovery room), so it is essential that information on these cases be provided as soon as possible, including the expected time between registration and discharge.

- A list of:

    - All surgeries from the past 6 months. In the case of a complaint survey concerning a surgery that took place further in the past, be sure to request a list that includes the month of the complaint case; and

    - All cases in the past year, if any, where the patient was transferred from the ASC to a hospital or where the patient died;

  The list should include each patient's name, age, type of surgical procedure scheduled or performed, and the name of the physician performing the procedure. The Coordinator explains to the ASC that, in order to complete the survey within the allotted time, it is important the survey team is given this information as soon as possible. The ASC should begin compiling this list as soon as the entrance conference concludes. Generally an ASC should be able to provide this information within 1 to 2 hours of the request.

- A location (e.g., conference room, an office not in use) where the survey team may meet privately during the survey, and also conduct record reviews, interviews, etc.;

- A telephone, preferably in the team meeting location;

- A list including the names of the Director of Nursing, active Medical Staff, Allied Health professionals, and all other staff providing patient care;

- A copy of the facility's organizational chart;

- Selected ASC written policies and procedures;

- Selected ASC personnel records;

- Written documentation related to the ASC's infection control program and its program for ongoing self-assessment of quality;

- A list of contracted services; and

- A copy of the facility's floor plan.

For initial or recertification surveys, arrange an interview with the administrative staff member who will be providing information enabling the survey team to complete the Form CMS-377, Ambulatory Surgical Center Request for Initial Certification or Update of Certification in the Medicare Program. Note that for recertification surveys, the ASC's management is not required to sign this form, since certification is ongoing and there is no requirement for the ASC to request recertification.

Task 3 – Information Gathering/Investigation

General Objective

The objective of this task is to determine the ASC's compliance with the CfCs through observations, interviews, and document review.

During the Survey

- Surveyors should always maintain a professional and calm demeanor;

- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. However, maintaining open and ongoing dialogue with the facility staff throughout the survey process generally enhances the efficiency and effectiveness of the survey. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey;

- Surveyors need to respect patient privacy and maintain patient confidentiality at all times during the survey;

- Surveyors are not permitted to conduct clinical examinations or provide clinical services to any of the ASC's patients. Surveyors may direct the attention of the ASC staff to address an immediate and significant concern affecting a patient's care. All significant issues or significant adverse events, particularly those that a surveyor believes may constitute an immediate jeopardy, must also be brought to the Team Coordinator's attention immediately. Immediate jeopardy is defined as a situation in which the ASC's noncompliance with one or more CfCs has caused, or is likely to cause, serious injury, harm, impairment or death to a patient. If the Team Coordinator agrees that there is an immediate jeopardy situation, the team will follow the guidance in Appendix Q of the State Operations Manual.

- Informal conferences with facility staff may be held in order to inform them of preliminary survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues;

- The survey team should meet at least daily in order to assess the status of the survey, progress of completion of assigned tasks, and areas of concern, as well as to identify areas for additional investigation. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues; and

- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided to the ASC upon request,

the surveyor is not a consultant and may not provide consulting services to the ASC.

Observations

Observations provide direct knowledge of the ASC's practices, which the surveyor must compare to the regulatory requirements in order to determine whether the ASC is in compliance with the requirements. The interpretive guidelines for each of the CfCs provide detailed guidance as to what the regulations require, as well as tips for surveyor activities to determine compliance.

Case Observation

The Team Coordinator should make it a priority at the beginning of the survey to select one or more surgical cases scheduled for observation during the survey. To form a more accurate picture of the ASC's routine practices, it is preferable to observe a case on the first day of the survey. ASC patients remain in the ASC up to a maximum of 24 hours; therefore, following individual cases from start to recovery or discharge is an effective tool for assessing the ASC's compliance with the CfCs. The number of cases selected will depend on the size of the team, the scheduled length of the survey, and the expected duration of the surgical case. Depending on the timing of the case selected, a surveyor may begin a case observation immediately.

The surveyor could follow the patient from pre-operative preparation and assessment to discharge (but at least through post-anesthesia recovery). For larger ASCs, i.e., those with more than 2 ORs or procedure rooms, or for multi-specialty ASCs, surveyors should consider following two cases.

In selecting cases to follow, surveyors should choose more complex cases, based on the type of procedure or patient age or patient co-morbidities. It may also be useful to avoid selecting cases where surveyors anticipate that patient modesty concerns may make it harder to obtain the patient's consent. As a general practice, to make efficient use of onsite time, surveyors should not select cases where the operative time is expected to exceed 90 minutes. Surveyors may opt not to observe the whole surgery from start to finish; however, in such cases they must assure they are in the OR when the patient is brought in, in order to observe the start of the surgery, and they must return to the OR before the case concludes. It may be useful for a surveyor to remain in the OR after the patient leaves, in order to observe how the OR is cleaned and prepped for the next case. In such cases the team should arrange for another surveyor to pick up the observation of the patient's care after the first surveyor leaves the OR.

In following the case(s) surveyors will look for evidence of compliance related to the various CfC requirements, e.g., infection control, physical environment, medication administration, assessment of anesthesia and procedure risk as well as the required pre-operative update assessment of changes from the history and physical, provision of surgical and anesthesia services, post-surgical assessment, recovery from surgery and anesthesia, and discharge orders.

ASC Tour

The tour may be accomplished before case observation, or surveyors who are not following a case may tour the ASC while the ASC staff is assembling the information requested during the entrance conference. The purpose of the tour is to get an overview of the whole ASC and to begin making findings about its compliance with the Cf C governing an ASC's environment, 42 CFR 416.44. The amount of time spent on the tour will depend on the size of the ASC, e.g., the number of ORs/procedure rooms, recovery rooms, etc. For revisit surveys, a tour of the whole facility is generally not necessary.

Observation Methods

When making observations, surveyors attend to the following; specific areas or activities to observe are discussed in the guidance for each CfC requirement.

- Building structure and layout, general appearance of cleanliness, odors;

- Staff-patient interactions, both clinical and non-clinical. For example, what happens to patients from the time they arrive at the ASC until the time they leave? Are their privacy and other rights protected? Is care provided by appropriate, qualified staff? Is patient identity verified by each staff member before care is provided?; and

- Other staff activities. For example, how do staff protect the confidentiality of medical records? Are infection control precautions observed? Are staff aware of regulatory requirements pertinent to their activities?

A surveyor must take detailed notes of all observations, identifying the regulatory standard(s) to which the observations relate to. For example, one set of observations might support findings related to multiple standards, or some surveyors may find it convenient to use interpretive guidance "tag" numbers as a convenient shortcut for identifying the applicable standards. When such tags are used, the surveyor must always recall that tags are just a filing/sorting device, and that the regulatory authority is always based on the specific regulatory language. With the approval of the SA, surveyors should also feel free to use templates or worksheets that will help record their survey findings.

Surveyors must attempt to obtain verification of the factual accuracy of their observations by the patient, family, facility staff, other team member(s), or by another means, as appropriate. For example, when finding an outdated medication on the anesthesia cart, surveyors can ask the ASC staff member who has responsibility for anesthesia to verify the drug's expiration date.

Surveyors must first obtain the permission of the patient or the patient's representative in order to observe the delivery of care to that patient. The privacy and dignity of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to observe his/her care. For observation of a surgical case, the patient's consent to the surveyor's observation must be included/added to the patient's informed consent. It is at the surveyor's discretion whether he or she prefers ASC staff to first approach a

patient about the possible observation of his or her procedure, or whether the surveyor approaches the patient directly to seek permission. In all cases, the surveyor must speak directly with the patient to obtain consent.

The surveyor is not required to obtain the consent of the operating physician prior to observing a surgical procedure. The surveyor may observe any and all cases and activities upon request as needed in order to assess compliance with the Medicare ASC CfCs. An ASC may not condition a surveyor's ability to observe patient care by, for example, requiring a surveyor to sign any written documents or to present proof of vaccinations. The surveyor, however, must ensure that his/her observation protects patient safety and does not interfere with the operating physician or the surgical procedure.

If a facility denies a surveyor access to ASC activities which must be evaluated to determine compliance with the Medicare ASC CfCs, then the facility has failed to provide evidence of compliance and must be cited accordingly. In addition, the ASC may be subject to exclusion from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. See "Regulatory and Policy References" section in this Appendix.

For each observation, the surveyor should document:

- The date and time of the observation(s);
- Location within the ASC;
- Patient and staff identifiers. A key containing identifiable information for patients must be kept on a separate identifier list. The ASC/surveyor may not use medical record numbers, Social Security numbers, or billing record numbers to identify patients, or the names or position numbers to identify staff members;
- Individuals present during the observation;
- Activity/area being observed (e.g., observation of sterile technique in the operating room, operative instrument cleaning and sterilization, recovery room care, etc).

Use of Infection Control Tool

CMS has developed, with the assistance of the Centers for Disease Control and Prevention (CDC), a comprehensive survey tool to assist surveyors in evaluating the infection control practices of an ASC. The tool may be found at Exhibit 351 of the State Operations Manual. One surveyor must be assigned to complete this tool during the survey, but all surveyors should be alert to breaches of standard infection control practices and share such observations with the surveyor completing the tool. The tool utilizes a combination of direct observations and interviews in order to document the ASC's infection control practices.

Document Review

ASCs maintain a variety of documents that provide evidence of their compliance/non-compliance with the regulations. Review of documents is a key component of the survey; however, it is important to note that the review must always be supplemented by surveyor observations and interviews. In particular, it is never sufficient to determine compliance by merely verifying that an ASC has an appropriate written policy and procedure in place. Surveyors must use a variety of means, including review of other documents, such as patient medical records, personnel files, maintenance records, etc., to confirm that the ASC actually follows its policies and procedures in its daily operations. Documents reviewed may be both written and electronic and include the following:

- Medical records (see discussion below);
- Personnel files to determine if staff members have the appropriate educational requirements and training, and are licensed and credentialed, if required. The ASC must comply with all CMS requirements and State law as well as follow its own written policies for medical staff privileging and credentialing;
- Maintenance records to determine if equipment is periodically examined and to determine whether the equipment is in good working order and whether environmental and sanitary requirements have been met;
- Policy and procedure manuals. When reviewing policy and procedure manuals, verify with the ASC's leadership that the manuals are current; and
- Contracts and transfer agreements. Review to verify these are current.

Photocopies

Surveyors must photocopy all documents needed to support deficiency findings. The surveyor requires access to a photocopier in the ASC in order to make these photocopies. Generally surveyors must not rely upon ASC staff to make copies for them. However, if the ASC insists that one of its staff must operate the copier, then a surveyor must observe the copying process, in order to assure that changes or omissions do not occur. If requested by the ASC, the surveyor will make an extra copy of the photocopied items for the ASC's benefit. All photocopies must be dated and timed by the surveyor to reflect when they were photocopied. They must be properly identified, as appropriate, e.g., "ASC Recovery Room Policy – 10-25-07 or "Facility Surgical Instrument Sterilization Policy – 10-25-07, or "Patient #3 Preoperative Anesthesia Assessment - 10-25-07."

Medical Record Review

Closed Record Sample Size and Selection

After the ASC provides a log or some other record of closed cases from the past six months, the team/surveyor will select a sample of the medical records for these cases to review.

Sampling for Initial Surveys, Recertification Surveys, or Representative Sample Validation Surveys

For recertification and representative sample validation surveys, the sample selected must represent a cross section of the cases performed at the ASC (i.e., different surgical specialties, types of surgery, surgical cases using different types of anesthesia, different physicians, post-op infection, unplanned post-operative transfer, etc.) The sample must include Medicare beneficiaries as well as other patients. All deaths and transfers to hospitals should be included. At a minimum, the surveyor selects at least 20 records for a facility with a monthly case volume exceeding 50. For lower volume ASCs, the surveyor selects at least 10 records. The sample size may be expanded as needed in order to determine compliance with the ASC CfCs, at the Team Coordinator's discretion.

Initial survey closed record sample sizes should be chosen at the Team Coordinator's discretion, since the volume of closed cases may be small. The Team Coordinator determines if there are enough patients on the current surgical schedule and patient records (i.e., open and closed) for surveyors to determine whether the ASC can demonstrate compliance with all CfCs for each specialty performed in the ASC.

Sampling for Complaint Surveys

CMS always assesses an ASC for its current compliance with the CfCs. Thus, it is not sufficient to look only at the medical record for the complaint case in conducting a complaint investigation. The surveyor must determine whether at the time of the survey the ASC is in compliance with the CfCs selected for evaluation. If evidence of noncompliance is found to have occurred in the past and the systems and processes that led to the noncompliance remain unchanged at the time of the survey, this will be treated as continuing current noncompliance.

The RO (for deemed ASCs) or the SA (for non-deemed ASCs) will determine in advance of the survey which CfCs the surveyors will be evaluating in relation to the complaint. Selection of the CfCs will be determined based on the nature of the allegation(s) explicitly stated or implied by the complaint – i.e., an allegation of transmission of an infectious disease will require review of the infection control CfC, and probably also of the governing body CfC, while an allegation by a hospital that it received an emergency transfer of a patient who had suffered a surgical complication that called into question the safety and competence of the ASC would necessitate reviewing multiple CfCs, including surgical services, medical staff, and governing body, at a minimum.

It will be necessary to review several closed records. The selection of the sample to review will be dependent, in part, on the complaint allegations. Depending on the CfCs to be surveyed for a complaint, it may also be necessary to observe an open case. If the complaint concerns infection control, for example, following a case will provide a good

opportunity to observe infection control practices throughout the ASC. On the other hand, if the complaint concerns a failure to assess patients preoperatively for risk, it would be more appropriate to look at a sample of closed records for the documentation of the assessments, as well as to observe portions of several open cases, as the patients move from registration into the OR or procedure room, to observe the pre-operative assessments.

A revisit survey may or may not require review of open or closed cases, depending on the specific standards and conditions being re-evaluated.

The surveyor must assign a unique identifier to each patient case observed/reviewed during the survey. A key containing identifiable information for patients must be kept on a separate identifier list. Do not use medical record numbers, Social Security numbers, or billing record numbers to identify the patients or names or positions for staff.

Once the medical records are available, surveyors can begin reviewing each record for evidence of compliance/noncompliance. The interpretive guidelines for the specific regulatory standards can be used if that is their primary assignment.

In reviewing the record surveyors should confirm whether it contains items required by various CfCs, including but not limited to:

- A comprehensive medical history and physical assessment completed not more than 30 days before the date of the surgery;
- Pre-surgical assessments – update of the H&P upon admission, and assessment for the risk of the procedure and anesthesia;
- Documentation of properly executed informed patient consent;
- Findings and techniques of the operation, including complications, allergies or adverse drug reactions that occurred;
- Orders signed by the physician for all drugs and biologicals administered to the patient;
- Documentation of adverse drug reactions, if any;
- Documentation of the post-surgical assessment of the patient, including for recovery from anesthesia;
- Documentation of reason for transfer to a hospital, if applicable;
- Discharge notes, including documentation of post-surgical needs; and
- Discharge order, signed by the operating physician.

Interviews

Interviews provide another method to collect information, and to verify and validate information obtained through observations, record review and review of other documents. Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews:

- Prepare detailed notes of each interview conducted. Document the interview date, time, and location, the full name and title of the person interviewed, and key points made and topics discussed. To the extent possible, document quotes from the interviewee.

- Interviews with facility staff should be brief and to the point.

- Interviews should be used to determine whether staff is aware of and understand what they need to do for the ASC to comply with regulatory requirements, as well as the ASC's formal policies and procedures. It is not necessary for staff to be able to cite specific Medicare regulations, but they should be able to describe what they do in a way that allows surveyors to determine compliance with the regulations.

- Be sure to interview staff having responsibilities related to each of the CfCs being surveyed.

- Use open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. For example, to determine if a staff member is aware of building emergency procedures, and his/her role in such events, simply ask, "If you smelled smoke, what would you do?" Do not ask, "Does this ASC have policies and procedures to address emergencies?" Likewise, ask, "Can you describe what typically happens in the OR before surgery begins?" Do not ask, "Does this ASC employ a standard 'time-out' procedure before beginning surgery?"

- Surveyors must always introduce themselves and ask patients or their representatives for permission to interview them. Surveyors must be sensitive when selecting patients for interview; for example, if a patient in recovery appears to still be feeling the effects of the anesthesia, an interview request should not be made. The same holds if a patient appears to be experiencing significant pain or anxiety. The privacy, dignity and well-being of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to conduct an interview.

- Patient interview questions should focus on factual matters about which the patient is likely to have information. For example, ask "Did the doctor discuss your surgery with you today? What information did the doctor discuss with you about the surgery?" "Did you notice whether people washed their hands or used a cleaning gel before providing care to you?"

- Problems or concerns identified during a patient or family interview must be addressed in the staff interviews to validate the patient's perception, or to gather additional information.

- Validate as much of the information collected via interviews as possible by asking the same question of several staff or patients, or by integrating interview responses with related surveyor observations or record review findings.

- If necessary, telephone interviews may be conducted for closed cases; however, in-person interviews are preferred.

Task 4 – Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews. The team's or surveyor's preliminary decision-making and analysis of findings assist in preparing the exit conference report.

Preparation

Prior to beginning this task, each surveyor must review his/her notes and completed worksheets related to observations and interviews, as well as the documents he/she has photocopied. The surveyor must be confident that he/she has everything needed to support his/her presentation of findings to the team, and to the SA manager when preparing a formal survey report.

Discussion Meeting

At this meeting, the surveyors share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement. For initial, recertification, and validation surveys, the Team should proceed sequentially through the regulatory requirements for each CfC; for complaint surveys they should proceed to review each CfC selected for investigation. The team must reach a consensus on all findings of noncompliance. Decisions about deficiencies must be team decisions, with each member having input. The team must document the evidence that supports each finding of noncompliance. Any additional documentation or evidence needed to support identified noncompliance must be gathered prior to exiting the facility.

All noted noncompliance must be cited as a deficiency, even when corrected onsite during the survey.

When a noncompliant practice is determined to have taken place prior to the survey, this would be considered evidence of current non-compliance, **unless** there is documentation that the ASC identified the problem prior to the survey and implemented effective corrective action. In evaluating whether the ASC is currently in compliance, the survey team must consider:

- What corrective action the facility implemented;

- Whether the corrective action was sufficient to address the underlying, systemic causes of the deficiency;

- Whether the corrective action was evaluated for its effectiveness to sustain long-term compliance; and

- Whether there are any other findings from the survey indicating current non-compliance.

If the deficient practice is identified and corrected by the ASC prior to the survey and there is no other evidence of current non-compliance, do not cite noncompliance.

In the case of a revisit survey, the surveyor's task is to determine current compliance with the regulatory requirements that were cited during the previous survey and ensure that the implementation of the written plan of correction submitted by the ASC and accepted by the SA was effective in maintaining long term compliance. The surveyor should conduct observations, document reviews and interviews to confirm current compliance with the CfC(s) addressed by the plan of correction.

Integrating Findings

The survey team integrates the findings derived from document review, observations, and interviews that pertain to each CfC surveyed, in order to make a determination of whether there is evidence of compliance/non-compliance.

Determining the Citation Level of Deficiencies

Citing noncompliance at the appropriate level, i.e., standard- or condition-level, is critical to the integrity of the survey process.

The regulations at 42 CFR 488.26 state, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a particular standard within the Conditions for Coverage is noted, the determination of whether the lack of compliance is at the Standard or Condition level depends upon the nature of the noncompliance – i.e., how serious is the deficiency in terms of its potential or actual harm to patients - and extent of noncompliance – i.e., is there noncompliance with the CfC stem statement, or how many different regulatory requirements within a CfC are being cited for noncompliance, or how frequent was a given noncompliant practice, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is sufficient to find condition-level noncompliance. Likewise, when an ASC has multiple standard-level deficiencies in a CfC, this may add up to pervasive non-compliance and could be sufficient to find condition-level noncompliance.

Determinations of citation level for complaint surveys follow the same process that is applied to full surveys; the only difference is that the complaint survey itself is generally limited to the CfCs implicated in the complaint.

Gathering Additional Information

If it is determined that the survey team needs additional information to determine facility compliance or noncompliance, the Team Coordinator determines the best way to gather such information.

Task 5 - Exit Conference

General Objective

The general objective of this task is to inform the ASC management of the team's preliminary findings.

Prior to the Exit Conference

- The Team Coordinator is responsible for organizing the exit conference, including who will have a speaking role.

- The health and Life Safety Code (LSC) surveyors/survey teams must have one joint exit conference if they are exiting at the same time; otherwise they may conduct separate exit conferences.

- If the team feels it may encounter a problem during the exit conference, the Team Coordinator should contact the SA manager in advance to discuss the potential problems and appropriate methods to handle them.

Discontinuation of an Exit Conference

CMS' general policy is to conduct an exit conference at the conclusion of all types of surveys. However, there are some comparatively rare situations that justify refusal to conduct or continue an exit conference. For example:

- If the ASC is represented by an attorney (all participants in the exit conference, both surveyor team members and ASC staff, must identify themselves prior to beginning the exit conference), surveyors may refuse to conduct the conference if the attorney attempts to turn it into an evidentiary hearing; or

- If the ASC staff /administration create an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the Team Coordinator stop the exit conference and call the SA for further direction.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape

recorders, recording the meeting simultaneously. The Team Coordinator should select one of the tapes at the conclusion of the exit conference to take back to the SA. Videotaping is also permitted, if the survey team agrees to this, and a copy is provided at the conclusion of the conference. The survey team is under no obligation to consent to videotaping and is not required to offer a reason if it refuses to permit videotaping.

General Principles

The following general principles apply when conducting an exit conference:

- The ASC management determines which ASC staff will attend the exit conference;

- The identity of individual patients or staff members must not be revealed by the survey team when discussing the survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference or characterization by which identity may be deduced; and

- Because of the information gathering activities the survey team has already engaged in, in most instances members of the ASC's staff should generally be aware prior to the exit conference of the areas, if any, where the survey team has concerns. Accordingly, there should be few cases where the ASC has not already had the opportunity prior to the exit conference to present additional information that might be relevant to the survey team's findings. The exit conference is not the correct setting for further information-gathering activities.

Exit Conference Sequence of Events

Introductory Remarks:

- Thank everyone for their cooperation during the survey;

- Reintroduce all surveyors who participated in the survey, even if they are no longer in the facility;

- Briefly reiterate what was the reason for the survey (i.e., initial, recertification, validation, or complaint); and

- Explain how the team will conduct the exit conference and any ground rules:

    - The exit conference is an informal meeting for surveyors to summarize their preliminary findings;

    - Brief comments on the findings may be made by the ASC, but will not be debated; and

    - Whether comments will be permitted in the middle of a surveyor's

presentation or only after the presentation has concluded.

Presentation of Findings

- Do not refer to any specific ASPEN software data tag numbers when describing deficiency findings. In the process of writing up the findings the SA will finalize just which tags/regulatory text to cite for each finding, so it would be premature to make such statements during the exit conference.

- Present the findings of noncompliance, explaining why the findings indicate noncompliance with the regulatory requirement. If the ASC asks for the pertinent regulatory reference, provide the citation for the applicable CfC.

- Do not make any general characterizations about the survey results (e.g., "Overall the facility is very good." or "In general the facility is in compliance with Medicare requirements.") Stick to presenting the specific factual findings.

- Do not make any statements about whether the findings represent condition-level or standard-level deficiencies. Avoid statements such as, "the condition was not met" or "the standard was not met." It is better to state "the requirement related to XXX is not met."

- If an immediate jeopardy situation was identified during the team discussion that the team had not previously discussed with the ASC's management, explain the significance and need for immediate correction. Follow instructions in Appendix Q, Guidelines for Determining Immediate Jeopardy.

- Do not rank findings. Treat requirements as equal as possible.

- Be certain that all deficiency findings are discussed at the exit conference.

Closure

- Indicate the official survey findings are presented in writing to the ASC via the Form CMS-2567, Statement of Deficiencies and Plan of Correction, which will be prepared and mailed to the ASC within 10 working days. It documents either that no deficiencies were found, or the specific deficiencies found, relating each to the applicable regulatory requirement. There will also be a letter communicating whether or not CMS will be taking enforcement action as a result of the survey's findings.

- The ASC's plan of correction (POC) and time frames for implementation of corrective actions are incorporated into the Form CMS-2567 and returned to the SA. Explain that the Form CMS-2567 is the document disclosed to the public about the facility's deficiencies and what is being done to remedy those (Form CMS-2567 with POC). The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey.

- If any deficiencies have been identified, inform the ASC that a written plan of correction must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies.

- Explain that, if a POC is required, the ASC will have the following three options:

    - Accept the deficiencies stated on Form CMS-2567 and submit a PoC;

    - Record objections to the cited deficiencies on Form CMS-2567 **and** submit a PoC; or

    - Record objections to cited deficiencies on Form CMS-2567, do not submit a PoC, but submit written arguments and documented evidence that the deficiencies are invalid.

        - CMS will consider objections and accompanying documentation that attempt to refute the factual accuracy of the survey findings, but will not entertain objections to CMS's judgment of the level, extent, scope or severity of a deficiency. CMS reviews additional documentation submitted by provider making an objection and, if the added evidence is convincing, will remove the deficiency.

        - If CMS disagrees with the ASC's objections, the ASC must submit an acceptable POC. Failure to submit an acceptable PoC or failure to correct a deficiency may result in termination of the ASC's supplier agreement in accordance with 42 CFR 488.28(a), and 416.35(b).

Explain that an acceptable plan of correction must contain the following:

- Action that will be taken to correct each specific deficiency cited;

- Description of how the actions will improve the processes that led to the deficiency cited;

- The procedure for implementing the corrective actions;

- A completion date for correction of each deficiency cited;

- Monitoring and tracking procedures to ensure the POC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;

- The title of the person responsible for implementing the acceptable plan of correction; and

- The administrator's signature and the date signed on Page 1 of the Form CMS-

2567.

Indicate that the POC will be reviewed by the SA, or in some cases, the RO, to determine whether it is acceptable. If a POC is determined not to be acceptable, it will be returned to the ASC for revision.

State that in some cases, the SA will make an unannounced revisit survey to determine whether the ASC has come into compliance.

If the exit conference was audio- or videotaped, obtain a copy of the tape before exiting the facility.

All team members should leave the facility together immediately following the exit conference. If the facility staff provides further information for review, the team coordinator determines the best way to review the additional information. It is usually prudent for at least two individuals to remain if all of the team members do not leave at the same time.

Task 6 – Post Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each SA and RO must follow the instructions in the SOM including:

- Timelines for completing each step of the process;
- Responsibilities for completing the Form CMS 2567, "Statement of Deficiencies," following the "Principles of Documentation;"
- Notification to the ASC regarding survey results;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the RO for further action/direction, such as concurrence with findings for deemed ASCs, authorization of a full survey for deemed ASCs with condition-level deficiencies); and
- Compilation of documents for the supplier's file.

Survey Package

The Team Coordinator will assign responsibilities for completion of the various elements of the survey package.

Statement of Deficiencies Report & Plan of Correction

The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with Federal requirements. Also, it is the form that the ASC will use to submit a plan to achieve compliance. Form CMS-2567 is an official record and is available to the public on request.

Indicate on Form CMS-2567 whether any deficiency constitutes immediate jeopardy to the individual's health and safety.

Write each deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand what regulatory requirements were not met. The consequence for incorrectly or unclearly documenting deficiencies can be the inability of CMS to take needed enforcement action.

Refrain from making clinical judgments. Instead, focus on the ASC's policies and procedures, as well as how they were or were not implemented by the ASC's medical and other staff.

After you complete Form CMS-2567 in ASPEN, submit it to your supervisor for review. If, after reviewing the form, your supervisor approves what you have documented, you will begin working on the remainder of the survey package. If your supervisor does not approve the form, then you will make any requested changes.

Other Survey Package Documentation
Complete the following documentation in hard copy. For complaint investigations, attach these materials to the corresponding complaint in the Aspen Complaint Tracking System:

- Description of sample selection;
- Summary listing of sample cases;
- Summary of interviews;
- Complaint investigation narrative;
- Form CMS-378E Ambulatory Surgical Center Crucial Data Extract
- For all surveys with a Life Safety Code component, Form CMS-2786U Fire Safety Survey Report; and
- Form CMS-670, Survey Team Composition and Workload Report

Part II

General Provisions and Definitions; General Conditions and Requirements

Interpretive Guidelines

Q-0001

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.25 Basic Requirements

Participation as an ASC is limited to facilities that –

(a) Meet the definition in §416.2; and

(b) Have in effect an agreement obtained in accordance with this Subpart.

Interpretive Guidelines: §416.25

An ASC must satisfy all the elements of the definition of an ASC and have in effect an agreement to participate as an ASC in order to satisfy the basic Medicare ASC requirements.

Q-0002

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.2 Definitions

As used in this part:

Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in Subpart B and C of this part.

Interpretive Guidelines: §416.2

According to the definition of an Ambulatory Surgical Center, or ASC, its key characteristics are that it:

- Is a distinct entity;

- Operates exclusively for the provision of surgical services to patients not requiring hospitalization, with the ASC's services expected not to exceed 24 hours in duration following an admission;

- Has an agreement with Medicare to participate as an ASC; and

- Complies with the Conditions for Coverage (CfCs) in Subparts B and C, i.e., 42 CFR 416.25-52.

Distinct Entity

An ASC satisfies the criterion of being a "distinct" entity when it is wholly separate and clearly distinguishable from any other healthcare facility or office-based physician practice. The ASC is not required to be housed in a separate building from other healthcare facilities or physician practices, but, in accordance with National Fire Protection Association (NFPA) Life Safety Code requirements (incorporated by cross-reference at §416.44(b)), it must be separated from other facilities or operations within the same building by walls with at least a one-hour separation. If there are State licensure requirements for more permanent separations, the ASC must comply with the more stringent requirement.

An ASC does not have to be completely separate and distinct physically from another entity, if, and only if, it is temporally distinct. In other words, the same physical premises may be used by the ASC and other entities, so long as they are separated in their usage by time. For example:

- **Adjacent physician office:** Some ASCs may be adjacent to the office(s) of the physicians who practice in the ASC. Where permitted under State law**, CMS permits certain common, non-clinical spaces,** such as a reception area, waiting room, or restrooms to be shared between an ASC and another entity, as long as they are never used by more than one of the entities at any given time, and as long as this practice does not conflict with State licensure or other State law requirements. In other words, if a physician owns an ASC that is located adjacent to the physician's office, the physician's office may, for example, use the same waiting area, as long as the physician's office is closed while the ASC is open and vice-versa. **The common space may not be used during concurrent or overlapping hours of operation of the ASC and the physician office**. Furthermore, care must be taken when such an arrangement is in use to ensure that the ASC's medical and administrative records are physically separate. During the hours that the ASC is closed, its records must be secure and not accessible by non-ASC personnel.

  Permitting use of common, non-clinical space by distinct entities separated temporally does not mean that the ASC is relieved of the obligation to comply with the NFPA Life Safety Code standards for ASCs, in accordance with

§416.44(b), that require, among other things, a one-hour separation around all physical space that is used by the ASC and fire alarms in the ASC.

It is not permissible for an ASC during its hours of operation to "rent out" or otherwise make available an OR or procedure room, or other clinical space, to another provider or supplier, including a physician with an adjacent office.

- **Facilities with Diagnostic Imaging and Surgery Capability:** Some facilities are equipped to perform both ambulatory surgeries and diagnostic imaging. However, Medicare regulations do not recognize a non-hospital institutional healthcare entity that performs both types of services, and actually requires an ASC to operate exclusively for the purpose of providing surgical services. However, the Medicare Independent Diagnostic Testing Facility (IDTF) payment regulations at 42 CFR 410.33(g) prohibit IDTFs that are not hospital-based or mobile from sharing a practice location with another Medicare-enrolled individual or organization. As a result, ASCs may not share space, even when temporally separated, with a Medicare-participating IDTF.

  NOTE: Certain radiology services integral to surgical procedures may be provided when the facility is operating as an ASC.

- **Separately Certified ASCs Sharing Space:** Where permitted under State law, several different ASCs, including ones that participate in Medicare and ones that do not, may use the same physical space, including the same operating rooms, **so long as they are temporally distinct,** i.e., they do not have concurrent or overlapping hours of operation. However, an ASC and a hospital or CAH outpatient surgery department, including a provider-based department that is either on or off the hospital's or CAH's main campus, may not share the same physical space, since the regulations at 42 CFR 413.65(d)(4) require that the provider-based department be held out to the public as a part of the main hospital, and that patients entering the provider-based facility are aware that they are entering the hospital.

  Each of the different ASCs that utilize the same space is separately and individually responsible for compliance with all ASC Conditions for Coverage (CfCs). So, for example, each ASC must have its own policies and procedures and its own medical records. Likewise, although there is no prohibition against each ASC using the same nursing and other staff under an arrangement with the employer of the staff, each is nevertheless required to separately comply with all requirements governing the utilization of staff in the ASC.

  At the same time, each Medicare-certified ASC that shares the same space as another Medicare-certified ASC should be aware, when entering into such an arrangement, that identification of certain deficient practices may result in citation of deficiencies for all ASCs occupying the same premises. For example, building features that violate the Life Safety Code would not vary according to which ASC happened to be operating on the premises at the time of a survey, and all ASCs at that location would be cited for the deficiency.

If there are multiple ASCs utilizing the same space, but at different times, it may be prudent to consider organizing recertification surveys in order to use the time on-site to conduct multiple surveys allowing assessment of each ASC that utilizes the space.

Exclusive Provision of Limited Surgical Services

The ASC must offer only surgical services. Separate ancillary services that are integral to the surgical services, i.e., those furnished immediately before, during or immediately after a surgical procedure, may be provided. The ASC may not, however, offer services unrelated to the surgeries it performs.

What constitutes "surgery"?

For the purposes of determining compliance with the ASC definition, CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons (**www.facs.org/fellows_info/statements/st-11.html**.) Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery:

> Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system, is also considered to be surgery. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician.) All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

An ASC is further limited to providing surgical services only to patients who do not require hospitalization after the surgery. Further, the ASC's surgical services must be ones that ordinarily would not take more than 24 hours, including not just the time for the surgical procedure but also pre-op preparation and recovery time, following the admission of an ASC patient. These limitations apply to all of the ASC's surgical services, not just to surgeries on Medicare beneficiaries who use the ASC.

- The term "hospitalization" means that a patient needs a supervised recovery period in a facility that provides hospital inpatient care. Whether a patient "requires" hospitalization after a surgical procedure is a function both of the characteristics of the patient and of the nature of the surgery. In other words, an ASC might be an appropriate setting for a particular surgical procedure for

patients under the age of 65 without significant co-morbidities, but might be a very risky, inappropriate setting for that same procedure when performed on a 75-year old patient with significant co-morbidities. ASCs must consider patient-specific characteristics that might make hospitalization more likely to be required when determining their criteria for patient selection.

Any surgery for which a patient must be routinely transferred to a hospital after the surgery is not appropriate for the ASC setting.

Some States permit the operation of "recovery centers" that are neither Medicare-certified healthcare facilities nor licensed hospitals, but which provide post-operative care to non-Medicare ASC patients. If such recovery centers would be considered hospitals if they participated in the Medicare program, then it is doubtful that an ASC that transfers patients to such centers meets the Medicare definition of an ASC. However, surveyors are not expected to make determinations about the nature of such recovery centers. If a SA is concerned that a recovery center is providing hospital inpatient care, it should discuss this matter further with the CMS Regional Office.

- Expected duration of services. ASCs may not provide services that, under ordinary circumstances, would be expected to exceed 24 hours following an admission. Patients admitted to an ASC will be permitted to stay 23 hours and 59 minutes, starting from the time of admission (see 73 FR at 68714 (November 18, 2008)). The time calculation begins with the admission and ends with the discharge of the patient from the ASC after the surgical procedure. While the time of admission normally would be the time of registration or check-in of the patient at the ASC's reception area, for the purposes of compliance with this requirement ASCs may use the time when the patient moves from the waiting/reception area into another part of the ASC. This time must be documented in the patient's medical record. The discharge occurs when the physician has signed the discharge order and the patient has left the recovery room. Other starting or end points, e.g., time of administration of anesthesia, or time the patient leaves the OR, may not be used to calculate compliance with the 24-hour requirement.

This requirement applies to all ASC surgical services. For services to Medicare beneficiaries there are additional payment regulations that further limit the surgical services that Medicare will pay for. For example, payment regulations at §416.166(b) state, among other criteria, that Medicare will generally pay for surgical procedures for which standard medical practice dictates that the beneficiary would not typically require active medical monitoring and care after midnight of the day of the procedure. This more restrictive Medicare payment requirement is enforced through the claims payment and audit processes. The SA surveyors may not cite an ASC for failing to meet the definition of an ASC if instances of Medicare beneficiaries who remain in the ASC are identified, so long as they meet the 24-hour requirement.

Rare instances of patients whose length of stay in the ASC exceeds 24 hours do not

automatically mean that the ASC fails to meet the regulatory definition of an ASC and must be cited as out of compliance with this requirement. The regulatory language refers to surgical services whose "expected duration" does not exceed 24 hours. It is possible for an individual case to take longer than expected, due to unforeseen complications or other unforeseen circumstances. In such rare cases the ASC continues to be responsible for the care of the patient until the patient is stable and able to be discharged in accordance with the regulatory requirements governing discharge, as well as the ASC's policy. However, if an ASC has cases exceeding 24 hours more than occasionally, this might suggest that the facility is not in compliance with the definition of an ASC.

Cases that surveyors identify which exceed 24 hours must be reviewed further to determine whether the expected duration of services for the procedure in question, when performed on a patient with key clinical characteristics similar to those of the patient in the case, would routinely exceed 24 hours. Key clinical characteristics include, but are not limited to, age and co-morbidities. If the procedure is one that Medicare pays for in an ASC setting, then it can be assumed that the expected duration of services related to that procedure would not exceed 24 hours. If the procedure is not one that Medicare pays for in an ASC, then the ASC must provide evidence supporting its expectation that the services to the patient would not exceed 24 hours. Such evidence could include other cases in the ASC where similar patients (in terms of condition prior to surgery) undergoing the same procedure were discharged in 24 hours or less after admission.

In summary, exceeding the 24-hour time frame is expected to be a rare occurrence, and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with §416.25. In addition, review of the cases that exceed the time frame may also reveal noncompliance with CfCs related to surgical services, patient admission and assessment, and quality assurance/performance improvement.

ASCs should be aware that, to the extent that patients remain within the ASC for 24 hours or longer, for purposes of Life Safety Code requirements the ASC would be considered a "healthcare" rather than an "ambulatory" occupancy under the NFPA Life Safety Code.

Has a Medicare Supplier Agreement

An entity cannot be an ASC, as that term is defined in Medicare's regulations, if it does not have an agreement to participate in Medicare as an ASC. Since ASCs are suppliers, the ASC agreement is a supplier agreement. Thus, while Medicare regulations recognize, for example, non-participating hospitals and will pay them for emergency services under certain circumstances, in the case of an ASC, the term "ASC" has a meaning exclusive to the entity's participation in the Medicare program. Applicants to participate as an ASC are not considered "ASCs" until they actually have a Medicare agreement in place.

In the case of a prospective ASC undergoing an initial survey to determine whether it

may be certified for Medicare participation, the SA may not conduct the survey until the Medicare Administrative Contractor/legacy Carrier has reviewed the ASC's Form 855B enrollment application and made a recommendation for approval of the ASC's participation in Medicare.

Compliance with Subparts B and C

Finally, an ASC must comply with each of the requirements found in Subparts B and C, i.e., the provisions found at 42 CFR 416.25 – 35 for Subpart B, and 42 CFR 416.40 – 52 for Subpart C.

Subpart B contains the supplier agreement requirements for an ASC. Enforcement of these provisions generally follows the same process as that outlined in SOM §3030. Although §3030 specifically addresses failures of providers to comply with the statutory provider agreement requirements, noncompliance of an ASC supplier with the provisions of Subpart B may be handled by CMS Regional Offices in the same way.

Subpart C contains the health and safety standards for ASCs, i.e., the Conditions for Coverage. State Survey Agencies survey ASCs for their compliance with the ASC definition and the CfCs. If an ASC has condition-level noncompliance with numerous CfCs, then condition-level noncompliance with §416.25 may also be cited.

Survey Procedures: §416.2

- Determine through interview and observation and consultation with the LSC surveyor whether the ASC facility is physically separated by at least a 1 hour separation from any other healthcare facility or physician office.

- Determine whether it is permissible under State licensure requirements for an ASC to share its physical space with another entity from which it is temporally separated. If sharing physical space that is temporally separate is not permitted under State law, then it is also not permitted under Medicare.

- Where permitted under State law, if the ASC shares common administrative space with an adjoining or contiguous physician's office or clinic, ask the ASC for evidence that use of this common space by the ASC and the other entity(ies) is not concurrent or overlapping in time. Look for signs or schedules that would confirm that the entities do not use the space at the same time.

- If an ASC complies with all other elements of the ASC definition but has permitted concurrent use by an adjacent physician's office or clinic of common administrative space, this would constitute a standard-level violation. However, co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in a condition-level violation of §416.25 and possibly the other CfCs.

- Where sharing of space by multiple healthcare entities is permitted under State law, determine through interview, observation and review of facility documents whether the ASC shares the same space, including clinical space, such as ORs, procedure rooms, recovery rooms, etc., with another entity.

    - If it does share space with other healthcare entities, ask the ASC for evidence that the two entities never operate concurrently or have overlapping hours. Look for signs or schedules that would confirm that the entities do not use the same space at the same time.

    - If there are multiple ASCs utilizing the same space and there are deficiencies that are common to more than one ASC, citations must be issued to each ASC.

    - If there is evidence that ASC and another entity that provides services other than surgery share the same space, including clinical space, concurrently or have overlapping hours of operation, this would constitute a condition-level violation of §416.25 because the ASC would not be a distinct entity and it would not be operating exclusively to provide surgical services. In addition, co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in additional condition-level violations.

    - If there is evidence that ASC and another entity that provides surgical services share the same space, including clinical space, concurrently or have overlapping hours of operation, this would constitute a standard-level violation. However, this co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in condition-level violation of §416.25 and possibly the other CfCs.

- Review all closed medical records in the survey sample to determine whether the time elapsed between the patient's admission or registration and discharge does not exceed 23 hours and 59 minutes. The calculation of the timeframe begins with the time documented in the medical record indicating when the patient moved from the reception or waiting area into another part of the ASC, if the ASC records this separate from the time of admission in the medical record.

- Determine whether the medical records note the patient's admission and discharge time.

- Observe whether the ASC correctly notes the time of admission for patients checking in and being discharged.

- For cases reviewed that exceed the permitted expected time frame, ask the ASC to provide documentation indicating why it was reasonable to have expected that the

time from admission to discharge would not exceed 24 hours. Acceptable evidence could include, but is not limited to, documentation that the procedure is one that Medicare has previously paid the ASC for, or other cases in the ASC involving the same procedure on similar patients that did not exceed the timeframe. ASCs may produce other evidence for surveyors to assess. Surveyors are not expected to know all of the surgical procedures covered by Medicare in an ASC, although they may obtain more information about this if they choose at http://www.cms.hhs.gov/apps/ama/license.asp?file=/ascpayment/downloads/CMS_1404_FC_ASC_AddAA_BB_DD1_DD2_EE.zip (This link requires a consent to use policies and then leads to a series of spreadsheets; the pertinent one is the ASC Addendum AA.) It is the responsibility of the ASC to demonstrate that the procedure is covered by Medicare when performed in an ASC.

Q-0020

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.40 Condition for Coverage: Compliance With State Licensure Law

The ASC must comply with State licensure requirements.

Interpretive Guidelines: §416.40

State licensure requirements generally exist for both healthcare facilities and healthcare professionals. States vary considerably in their licensure requirements for entities that meet the Medicare definition of an ASC. Some States may not require separate licensure of these facilities, although all States require licensure of healthcare professionals providing services within the ASC. Some States may require separate licensure for some, but not all ASCs within their State; for example, in some States, ASCs that are operated as part of a physician single or group private practice may not require separate licensure as a healthcare facility. This condition requires that an ASC comply with whatever State licensure requirements are applicable to it.

In States where a separate facility license is required for a facility providing ambulatory surgical services, the ASC must have a current license that has not expired or been suspended or revoked. The ASC must also be in compliance with the State licensure requirements.

Failure of the ASC to meet State licensure law may be cited when the State has made a determination of noncompliance and has also taken a final enforcement action as a result. Citation of licensure deficiencies may represent an initial step rather than a final action or determination by the State licensure authority. Additionally, the Federal survey of the ASC focuses on current compliance or non-compliance, not past noncompliance. Thus, for example, evidence that an ASC had been assessed a civil monetary penalty by the State licensure authority in the previous year would not be grounds for citing the ASC for noncompliance with State licensure law, unless the State licensure authority indicates the

ASC remains noncompliant.

If as a result of a State citation of an ASC for deficiencies in its compliance with licensure requirements the ASC has ceased operations and no longer furnishes services, it would be considered to have voluntarily terminated its Medicare supplier agreement as of the last date on which it provided services to Medicare beneficiaries, in accordance with§416.35(a)(3). The SA must advise the RO of the ASC's cessation of business, and the RO will process a voluntary termination.

If at the time of the survey the ASC's State license has been revoked, suspended, or otherwise formally limited (e.g., admissions have been curtailed by the State), then the ASC is not in compliance with this condition and must be cited for a condition-level deficiency. Furthermore, survey of the rest of the CfCs cannot be completed, since the ASC is not providing surgical services to patients. The SA must advise the RO of such formal licensure enforcement actions and the RO will proceed with action to terminate the ASC supplier agreement, in accordance with standard termination procedures.

If the surveyor identifies a situation that suggests the ASC may not be in compliance with State licensure law, the information may be referred to the State licensure authority for follow-up.

While States vary as to the types of healthcare professionals that require licensure, all ASCs have physicians and nursing staff that require State licensure. It is the ASC's responsibility to verify that all ASC personnel who require a State license have a current license that has not expired or been suspended or revoked.

Survey Procedures: §416.40

- Determine prior to the survey whether a facility license is required for the ASC. If there is access to State licensure files, review the ASC's State licensure status. Otherwise, ask to see the ASC's license.

- Review the ASC's documentation of all personnel required to be licensed under State or local laws or regulations. Check that the ASC has evidence that all personnel requiring licensure have current licenses in good standing.

Q-0040

§416.41 Condition for Coverage: Governing Body and Management

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that the facility policies and programs are administered so as to provide quality healthcare in a safe environment, and develops and maintains a disaster preparedness plan.

Interpretive Guidelines: §416.41

The ASC must have a designated governing body that exercises oversight for all ASC activities. The governing body is responsible for establishing the ASC's policies, making sure that the policies are implemented, and monitoring internal compliance with the ASC's policies as well as assessing those policies periodically to determine whether they need revision. The regulation particularly stresses the responsibility of the governing body for:

- direct oversight of the ASC's quality assessment and performance improvement (QAPI) program (see 72 FR 50472, August 31, 2007) and 73 FR 68714, November 18, 2008;
- the quality of the ASC's healthcare services;
- the safety of the ASC's environment; and
- development and maintenance of a disaster preparedness plan.

In the case of an ASC that has one owner, that individual constitutes the governing body.

Although the governing body may delegate day-to-day operational responsibilities to administrative, medical, or other personnel, the ASC's governing body retains the ultimate responsibility for the overall operations of the ASC and quality of its services. The regulation also emphasizes the governing body's responsibilities in the areas of QAPI and disaster preparedness. Delegations of governing body authority should be documented in writing.

The governing body is responsible for creating a safe environment where ASC patients can receive quality healthcare services. This means the governing body is not only responsible for adopting formal policies and procedures that govern all operations within the ASC, but also that it must take actions to ensure that these policies are implemented. Through its direct oversight and accountability for the ASC's QAPI program, it is expected that the ASC is better able to improve care being furnished to its patients. (See 72 FR 51472, August 31, 2007.) When QAPI citations are made related to 42 CFR 416.43, particularly Standard (e), the citation at 42 CFR 416.41should also be considered.

If condition-level deficiencies are cited related to multiple other ASC CfCs, with the result that the ASC does not provide quality healthcare or a safe environment, then it is also likely that the ASC is not complying with the governing body CfC.

Survey Procedures: §416.41

- Ask the ASC for information about its governing body. If there are questions about who constitutes the ASC's governing body, it may help to review the information the ASC reported in Section 6 of its CMS Form 855B application, identifying those individuals with ownership interest or managing control of the ASC.

- Ask the ASC how frequently the governing body meets and what are the typical

items on its meeting agendas.

- Has the governing body delegated operational responsibility to a manager?
- Ask for an organizational chart of the ASC management. Ask who performs the following functions:
  - Human Resources;
  - Medical staff credentialing and granting of privileges;
  - Management of surgical services;
  - Management of nursing services;
  - Management of pharmaceutical services;
  - Management of laboratory (if applicable) and radiologic services;
  - Management of the ASC's physical plant;
  - Medical records maintenance;
  - Infection control;
  - Quality Assurance and Performance Improvement.
- Ask to see meeting minutes or other evidence that the ASC's policies and procedures have been formally adopted by the governing body.
- Ask to see meeting minutes or other evidence of how the governing body assures that its policies are implemented, and of how the governing body monitors internal compliance with and reassesses the ASC's policies. For example, is there any evidence of data collected and submitted to the governing body related to specific ASC policies?
- Ask to see meeting minutes or other evidence of how the governing body exercises ongoing oversight of and accountability for the ASC's QA/PI program. See the discussion of §416.43 for more detail on the regulatory requirements related to QA/PI.

Q-0041

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.41(a) Standard: Contract Services

When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

Interpretive Guidelines: §416.41(a)

The ASCs may contract with third parties for provision of the ASC's services, including the ASC's environment. However, such a contract does not relieve the ASC's governing body from its responsibility to oversee the delivery of these ASC services. Given that many ASCs operate closely with a physician practice or clinic, or that some ASCs share space with other ASCs or other types of healthcare facilities operating at different times, use of a wide range of contract services may be common in ASCs. The ASC must assure that the contract services are provided safely and effectively. Contractor services must be included in the ASC's QAPI program.

For example:

- If the ASC contracts for cleaning of the ASC, including its ORs/procedures rooms, the ASC's governing body is still responsible for the sanitary condition of the ASC and must exercise oversight over its contractor to assure that standard sanitary practices are employed.

- If the ASC contracts for the provision of nursing services, the ASC remains responsible for assuring that all contract nurses are properly licensed and trained and oriented to perform their duties within the ASC. The ASC is responsible for the direction of nursing staff, regardless of whether they are employees or provided under contract.

- If the ASC contracts for provision of anesthesia services, the ASC remains responsible for reviewing the credentials of all anesthesiologists and anesthetists providing anesthesia services and granting them privileges to do so.

- If the ASC contracts (for example, with an associated adjacent physician practice) for provision of receptionist services, the ASC is responsible for assuring that such services are provided in a manner that complies with the patients' rights CfC requirements.

- If the ASC contracts for medical records services, it must ensure that the contractor meets all requirements of the medical records CfC.

Survey Procedures: §416.41(a)

- Ask the ASC for a complete list of its currently contracted services.

- Review the personnel files of contract personnel to determine, as applicable, their credentials, privileges, evidence of training, evidence of periodic evaluation, etc.

- If the ASC is one that shares space (temporally separated) with other entities, ask

the ASC whether it contracts or has some other formalized arrangement with any of those other entities for services when the ASC is in operation. If employees of an entity other than the ASC perform services while the ASC is in operation, and the ASC has no contract or other formal documentation of an arrangement with the other entity that governs the provision of such services, then the governing body fails to exercise its responsibility for the administration of the ASC's programs.

- Ask the ASC how it assesses the safety and effectiveness of the services provided by each contractor, including how contractor services are incorporated into its QA/PI program. Select several contractors from the list and ask for documentation of the most recent assessment of each by the ASC.

- Ask the ASC management what process it uses to correct deficiencies in contracted services. Ask if there are any cases where it has identified deficiencies and taken corrective action, and if so, ask to see documentation of these cases.

Q-0042

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.41(b) Standard: Hospitalization

(1) **The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.**

(2) **This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter.**

(3) **The ASC must *periodically provide the local hospital with written notice of its operations and patient population served.***

Interpretive Guidelines: §416.41(b)(1-3)

Guidance pending and will be updated in future release.

Q-0060

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.42 Condition for Coverage: Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

Interpretive Guidelines: §416.42

The standard level tag for §416.42 (Q-0064) provides more detailed guidance on the requirements for performing surgical services in a safe manner, by qualified physicians. It permits standard-level citations for identified deficiencies.

The manner and degree of noncompliance identified in relation to the standard level tags for §416.42 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

Q-0061

(Rev.71, Issued: 05-13-11, Effective: 5-13-11-Implementation: 05-13-11)

§416.42(a) Standard: Anesthetic Risk and Evaluation

(1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

Interpretive Guidelines: §416.42(a)(1)

The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization. The assessment must be specific to each patient; it is not acceptable for an ASC to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient. The requirement for a physician to examine the patient immediately before surgery is not to be confused with the separate requirement at 42 CFR 416.52(a)(1) for a history and physical assessment performed by a physician, although it is expected that the physician will review the materials from such pre-admission examination as part of the evaluation. Nevertheless, this requirement does constitute one component of the requirement at 42 CFR 416.52(a)(2) for a pre-surgical assessment upon admission. In those cases, however, where the comprehensive history and physical assessment is performed in the ASC on the same day as the surgical procedure, the assessment of the patient's procedure/anesthesia risk must be conducted separately from the history and physical, including any update assessment incorporated into that history and physical. See the interpretive guidelines for§§416.52(a)(1) & (2).

The ASC must have approved policies and procedures to assure that the assessment of anesthesia-related and procedural risks is completed just prior to every surgical procedure. (Ideally, the ASC would conduct such an assessment prior to the patient's admission as well as immediately prior to surgery, but this is not specifically required by the regulations.)

The ASC's policies must address the basis or criteria used within the ASC in conducting these risk assessments, and must assure consistency among assessments.

The regulations do not specify the content or methodology to be employed in such assessments. As an illustrative example, an ASC might choose to incorporate consideration of a patient's ASA Physical Classification into its criteria. Although the American Society of Anesthesiologists did not create its ASA Physical Status Classification System for the purpose of predicting operative risk, this system has nevertheless been found to be useful in predicting morbidity and mortality in surgical patients[1] and has been used by surgical facilities as a standard tool. This system classifies patients' physical status in 6 levels:

ASA PS I – Normal healthy patient;
ASA PS II – Patient with mild systemic disease;
ASA PS III – Patient with severe systemic disease;
ASA PS IV – Patient with severe systemic disease that is a constant threat to life;
ASA PS V – Moribund patient who is not expected to survive without the operation; and
ASA PS VI – Declared brain-dead patient whose organs are being removed for donor purposes.

As the ASA PS level of a patient increases, the range of acceptable risk associated with a specific procedure or type of anesthesia in an ambulatory setting may narrow. An ASC that employed this classification system in its assessment of its patients might then consider, taking into account the nature of the procedures it performs and the anesthesia used, whether it will accept for admission patients who would have a classification of ASA PS IV or higher. For many patients classified as ASA PS level III, an ASC may also not be an appropriate setting, depending upon the procedure and anesthesia.

If a State establishes licensure limitations on the types of procedures an ASC may perform that are based on patient classifications and would permit ASCs to perform fewer procedures than they would under the CfCs, then the ASC must conform to those State requirements. However, State requirements that would expand the types of procedures an ASC may offer beyond what is permitted under the CfCs are superseded by the Federal CfC requirements.

Endnotes for Standard: Anesthetic Risk and Evaluation

[1]P. 636, Davenport et al., "National Surgical Quality Improvement Program Risk Factors Can Be Used to Validate American Society of Anesthesiologists Physical Status Classification Levels," Annals of Surgery, Vol. 243, No. 5, May 2006

Survey Procedures: §416.42(a)(1)

- Verify that there is evidence for every medical record in the survey sample of an assessment by a physician of the patient's risk for the planned surgery and anesthesia.

- Ask the ASC to provide you with its policies and procedures for assessment of anesthesia and procedural risk. Check to determine that the policies include the criteria the ASC's physicians are to use in making the assessments.

- Ask the ASC's leadership to demonstrate how they assure a consistent approach in the assessment.

- Ask the ASC's leadership whether they can point to any cases where an assessment resulted in a decision not to proceed with the surgery. If there are no such cases, ask the ASC to explain how its patient selection criteria assure that there is an acceptable level of anesthesia and procedural risk for every patient scheduled for surgery in the ASC – for example, do they use patient admission criteria that exclude higher risk patients? If so, ask to see those criteria.

- The survey sample should include cases where a patient died or needed to be transferred to a hospital; discuss the pre-surgical assessment of the patient in those cases, preferably with the physician who conducted the assessments, to explore the basis on which the patient was found to be suitable for the surgery and anesthesia.

Q-0062

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.42(a) - Standard: Anesthetic Risk and Evaluation

(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

Interpretive Guidelines: §416.42(a)(2)

An evaluation of the patient's recovery from anesthesia, to determine whether the patient is recovering appropriately, must be completed and documented before the patient is discharged from the ASC. The American Society of Anesthesiology (ASA) guidelines do not define moderate or conscious sedation as anesthesia. While current practice dictates that the patient receiving conscious sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a postanesthesia evaluation is not required.

The evaluation must be completed and documented by a physician or anesthetist, as

defined at 42 CFR 410.69(b), i.e., a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant. See the discussion at §416.42(b) for more discussion of CRNA and anesthesiologist's assistant requirements.

ASCs would be well advised in developing their policies and procedures for postanesthesia care to consult recognized guidelines. For example, Practice Guidelines for Postanesthetic Care, Anesthesiology, Vol 96, No 3, March, 2002, provides the recommendations of the American Society of Anesthesiologists for routine postanesthesia assessment and monitoring, including monitoring/assessment of:

- Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
- Cardiovascular function, including pulse rate and blood pressure;
- Mental status;
- Temperature;
- Pain;
- Nausea and vomiting; and
- Postoperative hydration.

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

Survey Procedures: §416.42(a)(2)

- Review the ASC's policies and procedures regarding postanesthesia recovery and evaluation to determine if they are consistent with the regulatory requirement. Determine whether the ASC is following its own policy.
- Review a sample of medical records for patients who had surgery or a procedure requiring anesthesia to determine whether a postanesthesia evaluation was conducted for each patient.
- Determine whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia.
- Determine whether the evaluation was performed prior to the patient's discharge.

Q-0063

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.42(b) - Standard: Administration of Anesthesia

Anesthetics must be administered by only-

(1) A qualified anesthesiologist, or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

§416.42(c) - Standard: State Exemption

(1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and is effective upon submission.

Interpretive Guidelines: §416.42(b) & (c)

The ASC's policies and procedures must include criteria, consistent with State law governing scope of professional practice and other applicable State law, for determining the anesthesia privileges to be granted by the governing body to an eligible individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The ASC must specify the anesthesia privileges for each practitioner who administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and the ASC's policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

When granting anesthesia privileges to a physician who is not an anesthesiologist, the ASC's governing body must consider the practitioner's scope of practice, State law, the individual competencies, education, and training of the practitioner and the practitioner's compliance with the ASC's other criteria for granting physician privileges.

When an ASC permits operating physicians to supervise CRNAs administering anesthesia, the governing body must adopt written policies that explicitly provide for this.

A CRNA is defined at §410.69(b) as a "…registered nurse who:

(1) is licensed as a registered professional nurse by the State in which the nurse practices;

(2) meets any licensure requirements the State imposes with respect to non-physician anesthetists;

(3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) meets the following criteria:

(i) has passed a certification examination of the Council on Certification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition." A CRNA may administer anesthesia in an ASC when under the supervision of the operating physician.

If the ASC is located in a State where the Governor has submitted a letter to CMS attesting that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State, and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law, then a CRNA may administer anesthesia without physician supervision.

An anesthesiologist's assistant is defined at §410.69(b) as a "…person who – (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist's assistant education program that – (A) is accredited by the Committee on Allied Health Education and Accreditation; and (B) includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background." An anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed, meaning the anesthesiologist is:

- Physically present in the ASC; and

- Prepared to immediately conduct hands-on intervention if needed.

A trainee who is a physician in training to be an anesthesiologist in a recognized graduate medical education program, or a student in a recognized nurse anesthesia or anesthesiologist's assistance educational program may administer anesthesia in an ASC when supervised by the operating physician, in the case of a nurse anesthetist trainee, or by an anesthesiologist, in the case of a physician trainee or an anesthesiologist's assistant trainee.

Survey Procedures: §§482.42(b) and (c)

- Prior to the survey, determine whether the State has exercised its CRNA physician supervision opt-out option.

- Review the qualifications of individuals authorized to deliver anesthesia in the ASC, to determine whether they are consistent with the regulatory requirements.

- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

- If the ASC uses CRNAs, anesthesiologist's assistants or trainees, interview the ASC's leadership to determine how they are supervised. Do the medical records indicate that required physician supervision is provided?

- When observing a procedure, look for evidence of appropriately trained practitioners with supervision as required by the regulations.

Q-0064

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

Standard level tag for

§416.42 Condition for Coverage: Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

Interpretive Guidelines: §416.42

Qualified Physician: Surgery in an ASC may only be performed by a qualified physician. With respect to ASCs, a physician is defined in accordance with §1861(r) of the Social Security Act to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, and a doctor of podiatric medicine. In all cases, the physician must be licensed in the State in which the ASC is located and practicing within the scope of his/her license.

In addition, the regulation requires that each physician who performs surgery in the ASC has been determined qualified and granted privileges for the specific surgical procedures he/she performs in the ASC. The ASC's governing body is responsible for reviewing the qualifications of all physicians who have been recommended by qualified medical personnel and granting surgical privileges as the governing body determines appropriate.

The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials and determining whether to grant privileges and the scope of the privileges for each physician. See the interpretive guidelines for §416.45(a), Medical Staff Membership and Clinical Privileges for further guidance.

Safe Manner: The surgical procedures that take place in the ASC must be performed in a "safe manner." "In a safe manner" means primarily that physicians and other clinical staff follow acceptable surgical standards of practice in all phases of a surgical procedure, beginning with the pre-operative preparation of the patient, through to the post-operative recovery and discharge. Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.).

In addition, acceptable standards of practice include the use of standard procedures to ensure proper identification of the patient and surgical site, in order to avoid wrong site/wrong person/wrong procedure errors. Generally accepted procedures to avoid such surgical errors require:

- A pre-procedure verification process to make sure all relevant documents (including the patient's signed informed consent) and related information are available, correctly identified, match the patient, and are consistent with the procedure the patient and the ASC's clinical staff expect to be performed;

- Marking of the intended procedure site by the physician who will perform the procedure or another member of the surgical team so that it is unambiguously clear; and

- A "time out" before starting the procedure to confirm that the correct patient, site and procedure have been identified, and that all required documents and equipment are available and ready for use.

Conducting surgery in a safe manner also requires appropriate use of liquid germicides in the operating or procedure room. It is estimated that approximately 100 surgical fires occur each year in the United States, resulting in roughly 20 serious patient injuries, including one to two deaths annually. Fires occur when an ignition source, a fuel source, and an

oxidizer come together[1]. Heat-producing devices are potential ignition sources, while alcohol-based skin preparations provide fuel. Procedures involving electro-surgery or the use of cautery or lasers involve heat-producing devices. There is concern that an alcohol-based skin preparation, combined with the oxygen-rich environment of an anesthetizing location, could ignite when exposed to a heat-producing device in an operating room. Specifically, if the alcohol-based skin preparation is improperly applied, the solution may wick into the patient's hair and linens or pool on the patient's skin, resulting in prolonged drying time. Then, if the patient is draped before the solution is completely dry, the alcohol vapors can become trapped under the surgical drapes and channeled to the surgical site.

On the other hand, surgical site infections (SSI) also pose significant risk to patients; according to the Centers for Disease Control and Prevention (CDC)[2], such infections are the third most commonly reported healthcare associated infections. Although the CDC has stated that there are no definitive studies comparing the effectiveness of the different types of skin antiseptics in preventing SSI, it also states that "Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic."3 Hence, in light of alcohol's effectiveness as a skin antiseptic, there is a need to balance the risks of fire related to use of alcohol-based skin preparations with the risk of surgical site infection.

The use of an alcohol-based skin preparation in ASCs is not considered safe, unless appropriate fire risk reduction measures are taken, preferably as part of a systematic approach by the ASC to preventing surgery-related fires. A review of recommendations produced by various expert organizations concerning use of alcohol-based skin preparations in anesthetizing locations indicates there is general consensus that the following fire risk reduction measures are appropriate:

- Using skin prep solutions that are: 1) packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators; and 2) provide clear and explicit manufacturer/supplier instructions and warnings. These instructions for use should be carefully followed;

- Ensuring that the alcohol-based skin prep solution does not soak into the patient's hair or linens. Sterile towels should be placed to absorb drips and runs during application and should then be removed from the anesthetizing location prior to draping the patient;

- Ensuring that the alcohol-based skin prep solution is completely dry prior to draping. This may take a few minutes or more, depending on the

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[1] Tentative Interim Amendment (TIA 05-02) to (National Fire Protection Association) NFPA 99, 2005 edition, 13.4.1.2.2. Germicides and Antiseptics, issued July 29, 2005 and effective August 18, 2005. See also AORN Guidance Statement: Fire Prevention in the Operating Room; and Patient Safety Advisory June 2005 (Vol. 2 No. 2) 14, Prepared by ECRI for the Pennsylvania Patient Safety Reporting System.

[2] CDC Hospital Infection Control Practices Advisory Committee, "Guideline for Prevention of Surgical Site Infection, 1999," Infection Control and Hospital Epidemiology April 1999 (Vol. 20 No. 4) 251.

3 Ibid, p. 257

amount and location of the solution. The prepped area should be inspected to confirm it is dry prior to draping; and

- Verifying that all of the above has occurred prior to initiating the surgical procedure. This can be done, for example, as part of a standardized pre-operative "time out" used to verify other essential information to minimize the risk of medical errors during the procedure.

ASCs that employ alcohol-based skin preparations in ORs or procedure rooms should establish appropriate policies and procedures to reduce the associated risk of fire. They should also document the implementation of these policies and procedures in the patient's medical record.

Failure by an ASC to develop and implement appropriate measures to reduce the risk of fires associated with the use of alcohol-based skin preparations in ORs or procedure rooms is cited as condition-level noncompliance with §416.44.

Requirements addressed in other ASC Conditions for Coverage are important components of the provision of surgical services in a "safe manner," and condition-level deficiencies in these other areas may also constitute condition-level noncompliance with the Surgical Services Condition. These other pertinent ASC regulatory requirements include:

- §416.44(a)(1), concerning operating room design and equipment – for example:

    - The surgical equipment and supplies are sufficient so that the type of surgery conducted can be performed in a manner that will not endanger the health and safety of the patient;

    - Surgical devices and equipment are monitored, inspected, tested, and maintained by the ASC in accordance with Federal and State law, regulations and guideline, and manufacturer's recommendations; and that

    - Access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;

- §416.44(a)(2), concerning a separate recovery room;

- §416.44(a)(3) and §416.51, concerning infection control, for example:

    - The conformance to aseptic and, when applicable, sterile technique by all individuals in the surgical area;

    - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;

    - That operating room attire is suitable for the kind of surgical case

performed;

- That equipment is available for rapid "emergency" high-level disinfection or, as applicable, sterilization of operating room materials;

- That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture- and dust-controlled environment, and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.

- That, as applicable, temperature and humidity are monitored and maintained within accepted standards of practice; and

- §416.44(c) & (d), concerning emergency equipment and personnel – for example:

  - That surgical staff are trained in the use of emergency equipment.

Survey Procedures: §416.42

- Determine whether the ASC has policies and procedures that establish the criteria and process the governing body uses when granting surgical privileges to a physician. Ask for documentation that the governing body approved these policies and procedures.

- Ask the ASC to identify each physician who currently has surgical privileges or has had surgical privileges within the previous 6 months. Ask the ASC for documentation of the governing body's action to grant privileges to each of these physicians. Conduct this review in conjunction with the review of compliance with §§416.45(a)&(b).

- For each surgical case record that is reviewed as part of the survey team's medical record review, verify that the individual performing the surgery was a physician who had been granted privileges by the ASC's governing body.

- Observe at least one surgical case from the pre-operative phase through to the recovery room and discharge phase in order to determine whether standard procedures are followed to avoid wrong site/procedure/patient surgical errors, and that the requirements described above are met.

- Determine whether the ASC employs appropriate measures to reduce the risk of surgical fires.

- Ask the ASC whether it has ever had a surgical fire, and if so, what follow-up actions did it take to prevent the recurrence of surgical fires.

Q-0080
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.43 Condition for Coverage: Quality Assessment and Performance Improvement

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

Interpretive Guidelines: §416.43

The QAPI CfC requires an ASC to take a proactive, comprehensive and ongoing approach to improving the quality and safety of the surgical services it delivers. The QAPI CfC presumes that ASCs employ a systems approach to evaluating their systems and processes, identifying problems that have occurred or that potentially might result from the ASC's practices and getting to root causes of problems rather than just superficially addressing one problem at a time.

From a survey perspective, the focus of the QAPI condition is not on whether an ASC has any deficient practices, but rather on whether it has an effective, ongoing system in place for identifying problematic events, policies, or practices and taking actions to remedy them, and then following up on these remedial actions to determine if they were effective in improving performance and quality. QAPI programs work best in an environment that fixes problems rather than assigning blame.

For surveyors this can sometimes pose difficult challenges, because it requires a balancing act. ASCs are not relieved of their obligation to comply with all Medicare CfCs, and surveyors are obligated when they find evidence of violations of a CfC to cite accordingly. However, surveyors generally should avoid using the ASC's own QAPI program data and analyses as evidence of violations of other CfCs. For example, an ASC that identifies problems with infection control through its QAPI program and takes effective actions to reduce the potential for transmission of infection would be taking actions consistent with the QAPI CfC. Absent evidence independently collected by the surveyors of current noncompliance with the infection control CfC, it would not be appropriate for surveyors to use the infection control information in the ASC's QAPI program as evidence of violations of the infection control CfC. There can be egregious cases under investigation where it might be appropriate to use QAPI program information as evidence of a deficiency, but these cases should be the exception rather than the rule.

CMS does not prescribe a particular QAPI program; it provides each ASC with the flexibility to develop its own program. Each program must, however, satisfy the regulatory criteria:

- Ongoing – i.e., the program is a continuing one, not just a one-time effort. Evidence of this would include, but is not limited to, things like collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems

identified in the analyses, as well as new data collection to determine if the corrective actions were effective.

- Data-driven – i.e., the program must identify in a systematic manner what data it will collect to measure various aspects of quality of care; the frequency of data collection; how the data will be collected and analyzed; and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

Survey Procedures: §416.43

When there is a team surveying the ASC, survey of the QAPI Condition should be coordinated by one surveyor.

Q-0081

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.43(a) & §416.43(c)(1)

§416.43(a) Standard: Program Scope

(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

§416.43(c) Standard: Program Activities

(1) The ASC must set priorities for its performance improvement activities that –

(i) Focus on high risk, high volume, and problem-prone areas.
(ii) Consider incidence, prevalence and severity of problems in those areas.
(iii) Affect health outcomes, patient safety and quality of care.

Interpretive Guidelines: §416.43(a) & §416.43(c)(1)

There are a variety of types of indicators that are currently in use for measuring and improving quality of healthcare. This is also a rapidly changing field, as interest and research in patient safety and healthcare quality measurement grows. As a result of a recommendation of a 1998 Presidential Advisory Commission, the National Quality

Forum (NQF), a public-private not-for-profit membership organization, was created in 1999 to develop and implement a national strategy for healthcare quality measurement and reporting. Since then NQF has developed detailed recommendations for ways to promote and measure quality and patient safety, including in ASCs. The federal Agency for Healthcare Quality and Research (AHRQ) supports research assessing the effectiveness of care practices and procedures. A number of other organizations are also active in the field of healthcare quality improvement and patient safety. As a result, ASCs have many choices of indicators to use.

Indicators can be broken down into several types:

- **Outcomes Indicators** measure results of care; typical outcomes measures include risk-adjusted mortality rates, complication rates, healthcare-associated infection rates, length of stay, readmission rates, etc. In the ASC setting, outcomes measures might focus on things like complication rates, healthcare-associated infection rates, cases exceeding 24 hours, transfers to hospitals, wrong site surgeries, etc.

- **Process of Care Indicators** measure how often the standard of care was met for patients with a diagnosis related to that standard. For example, in the ASC setting, measures might focus on the administration and time of prophylactic antibiotics.

- **Patient Perception Indicators** measure a patient's experience of the care he/she received in the ASC. AHRQ sponsored development of one patient experience of care instrument, H-CAHPS, that CMS now uses in reporting on hospital quality. There may be similar patient survey instruments that could be used in the ASC setting.

The regulation at **§416.43(a)** requires that an ASC's QAPI program must improve both patient health outcomes and patient safety in the ASC. In order to achieve these goals, the ASC's QAPI program must:

1. Be ongoing – i.e., the program is a continuing one, not just a one-time effort or occasional effort. Evidence that the ASC's program is ongoing would include, for example, collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems identified in the analyses, as well as new data collection to determine if the corrective actions were effective.

2. Use quality indicators or performance measures associated with improved health outcomes in a surgical setting. The quality and safety indicators available differ in terms of the weight and type of evidence for their effectiveness in measuring quality. For some indicators there is compelling peer-reviewed research of an association with improved health outcomes. For others, typically process of care indicators, consensus among experts in the field suggests a strong association with improved quality of care. Indicators also differ in terms of how the data is collected, and how frequently the data should be collected.

   For example, measures of how quickly an ASC produces error-free billing claims,

while relevant to the ASC's financial performance and of interest to ASC governing bodies, have no direct relationship to the quality of care the ASC provides. On the other hand, a measure of the frequency with which the ASC administers antibiotic prophylaxis consistent with generally accepted standards of care would be related to improved health outcomes, i.e., prevention of surgical site infections. Likewise, an ASC could choose to collect data measuring its compliance with applicable National Quality Forum Safe Practices, or with applicable Centers for Disease Control and Prevention (CDC) infection control guidelines, or with guidelines issued by national professional societies, such as the American College of Surgeons, or with recommended practices developed by national accreditation organizations or other organizations specializing in healthcare quality improvement, such as the Institute for Healthcare Improvement. CMS does not prescribe a certain set of indicators/measures for ASCs to use, but ASCs must be able to demonstrate that the indicators they are tracking will enable them to improve outcomes for ASC patients.

The regulations at §416.43(c)(1) also require the ASC to set priorities in choosing its quality indicators/measures, because what is measured will determine where the ASC focuses its efforts to make changes that improve performance. For example, if the ASC does not track measures related to infection control, it will not be in a position to determine whether or not its infection control program is working well or poorly, and thus will not be in a position to improve it.

The ASC is required to focus on high risk, high volume, and problem-prone areas. It is required to consider, when selecting the measures/indicators that will shape its improvement activities in these areas, the following:

- The incidence, i.e., the rate or frequency at which problems occur in the ASC related to area measured by the indicator. "Incidence" is a technical term used in epidemiology, referring to the frequency with which something, such as a disease, appears in a particular population or area. In disease epidemiology, the incidence is the number of newly diagnosed cases during a specific time period. Applying this concept in the ASC setting, as an example, the annual incidence of surgical site infections in an ASC would be the rate that results when dividing the number of such infections that occurred in a calendar year by the total number of surgical cases in the ASC during that same year. Likewise, the annual incidence of emergency transfers to a hospital would be the rate that results when dividing the number of such transfers by the total number of surgical cases during the same year;

- The prevalence, i.e., how widespread something is in an ASC at a given point in time. "Prevalence" is also a technical term used in epidemiology, and is a statistical concept referring to the number of cases of a disease that are present in a particular population at a given time. In an ASC setting, for example, it would make little sense to employ measures related to prevalence of pressure ulcers among ASC patients, since the limited amount of time a patient typically spends in an ASC makes it unlikely that the ASC's care processes contributes to pressure ulcers. On the other hand a more appropriate measure might be periodic

observation of the hand hygiene practices of all staff providing direct patient care, in order to assess the prevalence of good versus deficient practices; and

- The severity of problems. For example, any single instance of a transfer of a patient to a hospital represents a serious adverse, unplanned outcome of the surgical procedure, and it would be appropriate for an ASC to track and evaluate all such cases, due to their severity, even if they are low volume incidents.

Once having identified the quality indicators it will use, the ASC must collect and analyze data on these indicators.

3. Identify and reduce medical errors/adverse patient events. Although there is no single, standard definition of a medical error or adverse event, the Institute of Medicine created a series of definitions related to patient safety that are helpful in understanding the regulatory requirement:

"An **error** is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."

"An **adverse event** is an injury caused by medical management rather than the underlying condition of the patient."

"An adverse event attributable to error is a **preventable adverse event**."[1]

Using these definitions, if an ASC performing orthopedic procedures operates on the right shoulder of a patient with a left shoulder rotator cuff injury requiring surgery, then the ASC has committed an error. The patient suffered an adverse event – i.e., the harm to the patient of undergoing surgery on the wrong shoulder, and presumably having to undergo yet another surgery on the correct shoulder. Because the ASC's error resulted in the adverse event, it is a preventable adverse event that could and should have been avoided.

Not every adverse event is the result of an error. For example, the standard of practice might call for use of a particular medication when certain indications are present. A patient might have an allergy to that medication that is unknown to the patient and the patient's physicians. The patient develops an allergic reaction to the medication, requiring further medical intervention to counteract the reaction. Due to the unknown nature of the patient's allergy, there was no error, even though there was an injury resulting from medical management. On the other hand, if the allergy had been documented in the patient's medical record and the medication had been administered anyway, this would constitute an error.

Not every error results in an adverse event; for example, an ASC with two operating rooms might mix up the records of two ASC patients scheduled to have the same orthopedic procedure, e.g., foot surgery, on the same date, but on the opposite feet. This is an error. But the ASC employs a time-out procedure to verify the identity of the patients and site of the surgery and recognizes the error

before surgery begins. The error did not result in an adverse event, but it was a near miss.

ASCs must track all patient adverse events, in order to determine through subsequent analysis whether they were the result of errors that should have been preventable, to reduce the likelihood of such events in the future. ASCs are also expected to identify errors that result in near misses, since such errors have the potential to cause future adverse events.

ASCs seeking initial enrollment in the Medicare program are unlikely to have collected extensive data for their QAPI program indicators, since they likely have been in operation for a relatively brief period of time. Nevertheless, these initial applicants must have a QAPI program in place, and must be able to describe how the program functions, including which indicators/measures are being tracked, at what intervals, and how the information will be used by the ASC to improve quality and safety.

Examples of ASC Quality/Patient Safety Indicators

The following information is based on the National Quality Forum's (NQF) consensus standards for ASCs, and is provided only as an illustration of several types of measures an ASC might choose to include in its QAPI program. An ASC is free to use different measures, so long as the measures it chooses meets the regulatory criteria. ASCs are also expected to develop additional measures related to infection control, for example to enable it to comply with the requirement at §416.51(b)(2) for its infection control program to be integrated into its QAPI program, and at §416.44(a)(3) to have a program to identify healthcare associated infections and report diseases as required under State law. Depending on the individual characteristics of the ASC, including problems it had experienced in the past, it may be necessary to track other additional indicators as well.

More information on these and other NQF ASC measures is available at:
http://www.qualityforum.org/pdf/ambulatory/tbAMBALLMeasuresendorsed%2012-10-07.pdf

- **Patient Burn** – Percentage of ASC admissions experiencing a burn prior to discharge. Approximately 100 surgical fires occur each year nationally, in all surgical settings, with about 20 resulting in serious injuries to patients.

- **Prophylactic Intravenous Antibiotic Timing** – Percentage of ASC patients who received appropriate antibiotics ordered for surgical site infection prophylaxis on time.

- **Hospital Transfer/Admission** – Percentage of ASC admissions requiring a hospital transfer or hospital admission prior to being discharged from the ASC.

- **Patient Fall** – Percentage of ASC admissions experiencing a fall in the ASC.

- **Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant**

- Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.

Survey Procedures: §416.43(a)

- Ask the ASC's leadership to describe the QAPI program, including staff responsibilities for QAPI and the quality/safety indicators being tracked.

- Ask what the rationale is for the particular indicators that the ASC has chosen to track. Are they based on nationally-recognized recommendations? If not, what evidence does the ASC have that the indicators it has chosen are associated with improvement in patient health outcomes and safety?

    - At a minimum, do the indicators include cases of patients transferred from the ASC to a hospital?
    - At a minimum, do the indicators include measures appropriate for surgery and infection control measures?

    - At a minimum, does the ASC have a system for tracking adverse patient events?

- Ask the staff responsible for QAPI what the method and frequency is for data collection for each QAPI program indicator.

[1]P. 28, ToErr is Human, Institute of Medicine, November, 1999.

Q-0082

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.43(b) and §416.43(c)(2) & (3)

§416.43(b) Standard: Program Data

(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.

(2) The ASC must use the data collected to –

(i) Monitor the effectiveness and safety of its services, and quality of its care.

(ii) Identify opportunities that could lead to improvements and changes in its patient care.

§416.43(c) Standard: Program Activities

(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that

improvements are sustained over time.

(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

Interpretive Guidelines: §416.43(b)& §416.43(c)(2) & (3)

Active Data Collection

The ASC must not only have identified a number of indicators or measures of quality and patient safety, but it must actively collect data related to those measures at the intervals called for by its QAPI program. Staff responsible for collection of the data should be trained in appropriate techniques to collect and maintain the data.

Data Analysis

Once having collected the data, the ASC must analyze it to monitor ASC performance, i.e., to determine what the data suggests about the ASC's quality of care and the effectiveness and safety of its services. Analysis must take place at regular intervals, in order to avoid too much time elapsing before the ASC is able to detect problem areas. In the case of data related to adverse events, the ASC must use the data to analyze the cause(s) of the adverse events. Data collection and analysis must be conducted by personnel with appropriate qualifications to collect and interpret quantitative data. CMS does not expect ASCs to engage in sophisticated statistical modeling of data, but calculation of incidence rates should be within the skill set of individual(s) conducting the analysis. On the other hand, CMS does expect ASCs to conduct thorough analyses that focus on systemic issues. For example, if the ASC's adverse event tracking system identifies a medication error that resulted in serious injury to a patient, the ASC would not be taking the type of systems approach mandated under the QAPI regulations if it states that the event was caused by the staff member who administered the medication incorrectly, and that its method for improving performance was to fire that staff member. An acceptable analysis would look at the root causes that facilitated the error by the staff member: Were medications stored in a manner that increased the possibility of error? Were the physician's orders clearly written? Was the staff member appropriately trained? Is there any evidence of similar errors made by other staff members, including errors that did not result in adverse events? There are probably additional issues that should be investigated in order to fully understand the causes of the adverse event. Once there is a thorough analysis of these causes, the ASC would then be in a better position to identify improvement strategies that are appropriately designed to address the underlying causes.

The ASC may choose to use contractors for technical aspects of the QAPI program, including analysis of data, but the ASC is also expected to actively involve ASC staff in the program and the ASC's leadership retains the responsibility for the ongoing management of the program, even when a contractor is used.

Analysis of the monitoring data must be used to identify areas where there is room for

improvement in the ASC's performance, as well as follow-up actions taken to improve performance. A good monitoring system, even in a good ASC surgical program, is likely to always find some areas of performance that are weaker than others. These identified areas of weakness present opportunities for the ASC to make changes in its systems, policies or procedures that result in improved patient care.

Implement Improvements/Preventive Strategies

Once the ASC's analysis of its data has identified opportunities for improvement, the ASC must develop specific changes in its policies, procedures, equipment, etc., as applicable, to accomplish improvements in the identified areas of weakness. In particular, an ASC must implement preventive strategies designed to reduce the likelihood of adverse events throughout the ASC. For example, if an ASC has three operating or procedure rooms, and it has an adverse event in a case in one of these rooms that is attributable in part to a confusing storage of emergency medications, the ASC should review the set up in each of the rooms to ensure that the same problem does not occur elsewhere.

Sustaining Improvements

The ASC must also have a method to ensure that the improvements it makes are sustained over time. For example, if an ASC's QAPI program identifies problems with hand hygiene in ASC staff providing care to patients, the ASC must be able to demonstrate that whatever solution it adopted to address this problem continues to work over time. Generally this means that the ASC must collect data on indicators that measure staff hand hygiene on an ongoing basis.

Staff Training

The ASC is required to make all staff aware of the strategies it has adopted for prevention of adverse events. For example, all staff who are involved in the preparation of a patient for the surgical procedure, as well as in the conduct of the surgical procedure, must be familiar with the ASC's strategies for avoiding wrong patient, wrong site, wrong side, wrong procedure, wrong implant, and adverse surgical events. All staff involved in the preparation and administration of injectable medications should be aware of standard safe injection practices designed to avoid the transmission of infectious disease. Staff should be encouraged to ask questions when they observe a practice, or receive an order, etc. that they believe might compromise patient safety or quality of care in the ASC.

Prospective ASC's Applying for Initial Certification in Medicare

A facility seeking initial certification as an ASC may not have been in operation long enough to demonstrate extensive data collection or the identification of opportunities for improvement based on the monitoring data. However, it must be able to show that it has an active data collection and analysis infrastructure in place as well as to indicate when it expects to have sufficient data to begin analysis and what procedures it has put in place to consider the results of QAPI program analyses.

Survey Procedures: §416.43(b)

- Ask the ASC to show you examples of quality and adverse event data it is collecting. Is the ASC collecting data on all of the indicators/measures it identified for its QAPI program? Is it collecting the data at the frequency specified in its QAPI program?

- Ask the ASC who is responsible for the data collection and analysis, and what their qualifications are? In particular, ask the ASC how it determines the causes of adverse events – does the ASC stop with the immediate cause (staff error, equipment failure, etc.) or does it probe to discover the underlying root causes of the adverse events?

- If ASC staff handle these duties, do they have education or training that equips them to conduct analyses of the data?

- Ask the ASC to provide examples of instances where it used QAPI data to identify opportunities for improving processes for providing care. Ask how it evaluated whether the improvements were effective and sustained.

- Ask the ASC how it trains staff on ways to prevent adverse events from occurring.

- Ask ASC staff what they know about the ASC's QAPI program, focusing in particular on staff awareness of policies and procedures for preventing adverse events.

Q-0083

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.43(d) Standard: Performance Improvement Projects.

(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.

Interpretive Guidelines: §416.43(d)

Every ASC must undertake one or more specific quality improvement projects each year. Larger ASCs with multiple ORs or procedure rooms, multiple types of surgical procedures offered, or high volume of cases are expected to undertake more or more complex projects. Furthermore, a highly complex improvement project might be of such scope that it could reasonably be the only project an ASC undertakes in a given year.

CMS does not specify particular projects that each ASC must undertake, but instead expects the projects to be based on the types of services the ASC furnishes, as well as other aspects of the ASC's operations. The requirement for annual projects does not mean that an ASC may not undertake a complex project that is expected to require more than 1 year in order to be completed.

The ASC must keep records on its performance improvement projects. Each project must, at a minimum, include an explanation of why the project was undertaken. The explanation must indicate what data collected in the ASC or based on recommendations of nationally recognized organizations leads the ASC to believe that the project's activities will actually result in improvements in patient health outcomes and safety in the ASC. For projects that are still underway, the ASC must be able to explain what activities the project entails, and how the impact of the project is being monitored. Unless the project has just begun, the ASC must be able to provide evidence that it is collecting data that will enable it to assess the project's effectiveness. For projects that are completed, the ASC must be able to show documentation that explains what the results of the project were, and what actions, if any, the ASC took in response to those results.

Survey Procedures: §416.43(d)

- Ask the ASC to show you documentation for performance improvement projects currently underway, as well as those completed in the prior year.

- If a large, complex, or high volume ASC has only one project underway, is the scope of that project such that it is likely to have a significant impact on the ASC's quality of care or patient safety?

- Does the ASC's documentation indicate the rationale for undertaking each project? Does the ASC have data indicating it had a problem in the area targeted for improvement, or could the ASC point to recommendations from a nationally recognized expert organization suggesting the activities?

- Does the documentation for the completed project(s) include the project's results? If a project was unsuccessful, ask the ASC what actions it took as a result of that information. If the project was successful, ask the ASC how it is sustaining the improvement.

Q-0084

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.43(e) Governing body responsibilities.

The governing body must ensure that the QAPI program –

(1) Is defined, implemented, and maintained by the ASC.

(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.

(3) Specifies data collection methods, frequency, and details.

(4) Clearly establishes its expectations for safety.

(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

Interpretive Guidelines: §416.43(e)

An ongoing, successful QAPI program requires the support and direction of the ASC's leadership. This regulation makes clear CMS' expectations that the ASC's governing body must assume responsibility for all aspects of the design and and implementation of every phase of the QAPI program. The governing body must assure that the ASC's QAPI program:

- Is defined, in writing, for example in the minutes of a meeting where the governing body established the program;
- Is actually implemented, with written evidence of this implementation, as well as evidence of knowledge of the program by the ASC's staff;
- Is implemented on an ongoing basis;
- Employs quality and patient safety indicators that reflect appropriate prioritization, as required by §416.43(c);
- Describes in detail the indicator data to be collected, how it will be collected, how frequently it will be collected;
- Uses the data collected and analyzed to improve the ASC's performance;
- Evaluates changes designed to improve the ASC's performance to determine whether they are effective, and takes appropriate actions to make further changes as needed;
- Is designed to establish clearly the governing body's expectations that patient safety is a priority, not only by the tracking of all adverse events, but also by the program's processes for analyzing and making changes in ASC operations to prevent future such events; and
- Has sufficient resources, i.e., the ASC's governing body must allocate sufficient and qualified staff (including consultants)**,** staff time, information systems and training to support the program. Given the great variety in size and complexity among ASCs, the extent of resources required will vary as well. However, the resources dedicated to the QAPI program must be commensurate with the ASC's

overall scope and complexity. The ASC must also be able to identify in detail the resources that it dedicates to the QAPI program.

Survey Procedures: §416.43(e)

- Does the ASC's QAPI program include all of the essential elements described above?

- Ask the ASC's leadership to explain how the governing body is involved in the QAPI program. Does the ASC's leadership display ready knowledge of the program's structure and activities. If a contractor is used for some portions of the program, does the ASC's leadership monitor closely the contractor's activities?

- Is there evidence of a governing body review of all elements of the QAPI program, e.g., meeting minutes?

- Ask the ASC's leadership how it uses the program to improve performance. Ask for evidence of changes made as a result of QAPI program activities.

- Ask the ASC's leadership for documentation of the details of the resources that are dedicated to the QAPI program. Is there evidence that these resources were actually made available as planned? For example, interview staff identified as having a role in the QAPI program to determine whether they actually perform QAPI functions, and for what percentage of their time. Is there evidence that planned data collections and analyses actually took place?

Q-0100

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.44 Condition for Coverage: Environment

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

Interpretive Guidelines: §416.44

The ASC must comply with requirements governing the construction and maintenance of a safe and sanitary physical plant, safety from fire, emergency equipment and emergency personnel.

Survey Procedures: §416.44

A surveyor trained in surveying for the applicable Life Safety Code standards must survey for compliance with the Safety from Fire Standard; the rest of the standards under this Condition are surveyed by Health surveyors.

Q-0101
(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.44(a) Standard: Physical Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

Interpretive Guidelines: §416.44(a)(1)

State Agencies may wish to assign surveyors who are trained in evaluating healthcare facility design and construction assist in evaluating compliance with this standard. "Operating room" (OR) in an ASC includes not only traditional ORs, but also procedure rooms, including those where surgical procedures that do not require a sterile environment are performed.

ORs must be designed in accordance with industry standards for the types of surgical procedures performed in the room, including whether the OR is used for sterile and/or non-sterile procedures. Existing ORs must meet the standards in force at the time they were constructed, while new or reconstructed ORs must meet current standards. Although the term "OR" includes both traditional ORs and procedure rooms, this does not mean that procedure rooms must meet the same design and equipment standards as traditional operating rooms. In all cases, the OR design and equipment must be appropriate to the types of surgical procedures performed in it.

National organizations, such as the Facilities Guidelines Institute, may be used as a source of guidance to evaluate OR design and construction in an ASC. If a State's licensure requirements include specifications for OR design and construction, the ASC must, in accordance with §416.40, comply with those State requirements.

The location of the OR within the ASC and the access to it must conform to accepted standards of practice, particularly for infection control, with respect to the movement of people, equipment and supplies in and out of the OR. The movement of staff and patients on stretchers must proceed safely, uninhibited by obstructions.

The OR must also be appropriately equipped for the types of surgery performed in the ASC. Equipment includes both facility equipment (e.g., lighting, generators or other back-up power, air handlers, medical gas systems, air compressors, vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment if applicable, OR tables, stretchers, IV infusion equipment, ventilators, etc.). Medical equipment for the OR includes the appropriate type and volume of surgical and anesthesia equipment, including surgical instruments. Surgical instruments must be available in a quantity that is commensurate with the ASC's expected daily procedure volume, taking into

consideration the time required for appropriate cleaning and, if applicable, sterilization. In addition, emergency equipment determined to be necessary in accordance with §416.44(c) must be either in or immediately available to the OR.

The OR equipment must be inspected, tested and maintained appropriately by the ASC, in accordance with Federal and State law (including regulations) and manufacturers' recommendations.

Temperature, humidity and airflow in ORs must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort. ASCs must maintain records that demonstrate they have maintained acceptable standards.

An example of an acceptable humidity standard for ORs is the American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities. Addendum D of the ASHRAE standard requires RH in ORs to be maintained between 20 - 60 percent. In addition, this ASHRAE standard has been incorporated into the Facility Guidelines Institute (FGI) 2010 Guidelines for Design and Construction of Health Care Facilities, and has been approved by the American Society for Healthcare Engineering of the American Hospital Association and the American National Standards Institute. ASCs must also ensure, however, that the OR humidity level is appropriate for all of their surgical and anesthesia equipment, and that supplies which require a different level of humidity than that in the OR are appropriately stored until used.

Each operating room should have separate temperature control. Acceptable standards for OR temperature, such as those recommended by the Association of Operating Room Nurses (AORN) or the FGI, should be incorporated into the ASC's policy.
Equipment for rapid emergency sterilization of OR equipment/materials whose sterility has been compromised must be available on-site. However, an ASC that routinely uses sterilization procedures intended for emergency use only as its standard method of sterilization between cases, in order to reuse surgical instruments, must be cited for violating §§416.44(a)(1) & (3) and the Infection Control Condition at §416.51.

It is not necessary for the ASC to have equipment for routine sterilization of equipment and supplies on-site, so long as this service is provided to the ASC under arrangement.

Survey Procedures: §416.44(a)

- Verify the ASC's ORs meet applicable design standards.

- Verify the ASC has the right kind of equipment in the ORs for the types of surgery it performs.

- Verify the ASC has enough equipment, including surgical instrument sets, for the volume of procedures it typically performs.

- Verify the ASC has evidence, such as logs on each piece of electrical or mechanical equipment, indicating that it routinely inspects, tests, and maintains the equipment.

- Verify who within the ASC is responsible for equipment testing and maintenance.

- Considering the size of the OR and the amount and size of OR equipment, verify there is sufficient space for the unobstructed movement of patients and staff.

- Review the ASC's temperature and humidity records for ORs, to ensure that appropriate levels are maintained and that, if monitoring determined temperature or humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels.

Q-0102

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.44(a) Standard: Physical Environment

[The ASC must provide a functional and sanitary environment for the provision of surgical services.]

(2) **The ASC must have a separate recovery room and waiting area**.

Interpretive Guidelines: §416.44(a)(2)

The ASC is required to have both a waiting area and a recovery room, which must be separate from each other as well as other parts of the ASC. They may not be shared with another healthcare facility or physician office. (See the interpretive guidelines for §416.2 concerning sharing of physical space by an ASC and another entity.)

There must be a room within the ASC where patients recover immediately after surgery. A "room" consists of an area with at least semi-permanent walls from floor to ceiling separating it from other areas of the ASC. The recovery room must be equipped to allow appropriate monitoring of the patient's recovery. The type of equipment required depends on the type(s) of surgery performed in the ASC. The size of the recovery room must be commensurate with the number of ORs in the ASC and the expected volume of patients who will be in recovery simultaneously.

The recovery room may also be used for preoperative preparation of patients as well as for post-operative recovery, consistent with accepted standards of practice. Under no circumstances, however, may the recovery room also be used as a general waiting area for patients awaiting preoperative preparation or for people who accompany patients. Likewise, patients recovering from surgery may not be placed in a waiting room or area,

unless they have already been discharged from the ASC and are, for example, waiting briefly while the adult who accompanied them brings a car to the ASC's entrance.

Consistent with accepted standards of practice, including infection control standards, and protection of patients' rights to privacy and confidentiality of their clinical information the ASC may permit individuals who accompany patients to be present in the recovery room during the patient's recovery from surgery.

Survey Procedures: §416.44(a)(2)

- Observe whether there is a separate room in which patients recover from their surgery, and whether it is appropriately equipped.

- Observe whether there is a separate waiting area for visitors and patients who have not yet begun preoperative preparation.

Q-0104

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(b) Standard: Safety From Fire

(1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health *Care Occupancies, regardless of the number of patients served, and must proceed in accordance with* the Life Safety Code *(NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).*

(2) In consideration of a recommendation by the State survey agency *or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate,* specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

Interpretive Guidelines: §416.44(b)*(1)-(3)*

Guidance pending and will be updated in future release.

Q-0105

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

Interpretive Guidelines: §416.44(*b*)*(4)*

Guidance pending and will be updated in future release.

Q-0106

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(5) When a sprinkler system is shut down for more than 10 hours, the ASC must:

> ***(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or***
>
> ***(ii) Establish a fire watch until the system is back in service.***

Interpretive Guidelines: §416.44(*b*)*(5)*

Guidance pending and will be updated in future release.

Q-0107

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(6) Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.

Interpretive Guidelines: §416.44(b)(6)

Guidance pending and will be updated in future release.

Q-0108

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(c) Standard: Building Safety.

Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

> ***(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.***
>
> ***(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.***

Interpretive Guidelines §416.44(c)

Guidance pending and will be updated in future release.

Q-0109

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(d) Standard: Emergency Equipment

The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements:

(1) ***Be immediately available for use during emergency situations.***

(2) ***Be appropriate for the facility's patient population.***

(3) ***Be maintained by appropriate personnel.***

Interpretive Guidelines §416.44(d)

Guidance pending and will be updated in future release.

Q-0110

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(e) Standard: Emergency Personnel

Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

Interpretive Guidelines: §416.44(e)

Guidance pending and will be updated in future release.

Q-0111

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(f) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

Q-0120

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.45 Condition for Coverage: Medical Staff

The medical staff of the ASC must be accountable to the governing body.

Interpretive Guidelines §416.45

The organization of the medical staff is left to the discretion of the governing body, but however the staff is organized, the ASC must have an explicit, written policy that indicates how the medical staff is held accountable by the governing body. The policy must address all requirements in this condition. Medical staff privileges may be granted both to physician and non-physician practitioners, consistent with their permitted scope of practice in the State, as well as their training and clinical experience.

It is possible for an ASC to be owned and operated by one physician, who could be both

the sole member of the governing body and also the sole member of the ASC's medical staff. In such cases the physician owner must nevertheless implement a formal process for complying with all medical staff regulatory requirements.

Survey Procedures §416.45

Ask the ASC's leadership for its policy detailing how the governing body holds the medical staff accountable.

Q-0121

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.45(a) Standard: Membership and Clinical Privileges

Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

Interpretive Guidelines §416.45(a)

All members of the ASC's medical staff and all clinicians granted medical staff privileges must be appointed to their position within the ASC by the ASC's governing body. They must be granted privileges by the governing body, in writing, that specify in detail the types of procedures they may perform within the ASC. It is not sufficient for the governing body to grant privileges to "perform surgery" or even to perform "orthopedic surgery." For example, an ASC that specializes in orthopedic surgery of various types must specify which types of procedures each surgeon is privileged to perform.

The ASC's governing body must assure that medical staff privileges are granted only to legally and professionally qualified practitioners.

"Legally qualified" means the practitioner has a current license to practice within the State where the ASC is located, and that the privileges to be granted fall within that State's permitted scope of practice. The ASC must verify that each practitioner has a current professional license and document the license in the practitioner's file.

"Professionally qualified" means that the practitioner has demonstrated competence in the area for which privileges are sought. Competence is demonstrated through evidence of specialized training and experience, e.g., certification by a nationally recognized professional board.

The governing body is also required to solicit the opinion of qualified medical personnel on the competence of applicants for privileges. The recommendation provided must be in writing, and should include a supporting rationale. The qualified medical personnel may be current members of the ASC's medical staff, but may also be physicians not practicing in the ASC. ASCs should consider seeking the recommendations of qualified outside

physicians when they do not have appropriate expertise in-house to evaluate the competency of an applicant for privileges. This is particularly advisable when the ASC's governing body consists of one physician owner who is also the sole member of the medical staff. The ASC's governing body is not required to accept the recommendation provided by the qualified medical personnel to grant, deny, or restrict privileges to a practitioner. However, when the ASC's governing body makes a decision contrary to the recommendation, it is expected to document its rationale for doing so.

The ASC should document the process by which the governing body grants medical staff privileges, including the documentation, or credentials, it reviews for each candidate, the criteria it uses in evaluating the candidate, how it selects the qualified medical personnel who make recommendations on the practitioner's qualifications, and whether and under what circumstances the governing body may make a privileging decision contrary to the recommendation of the qualified medical staff.

Survey Procedures: §416.45(a)

Ask the ASC's leadership to explain its process for granting clinical privileges.

Review the personnel records for all medical staff that have been granted clinical privileges.

There must at a minimum be documentation of:

- State licensure, registration, or state certification, as applicable;
- Certification by a specialty organization, as appropriate;
- Other training or pertinent experience;
- Evidence of a recommendation by qualified medical personnel concerning the practitioner's competence;
- The scope of the privileges granted to the practitioner; and
- If the governing body granted privileges against the recommendation of the qualified medical personnel, its rationale for doing so.

Does the review of each practitioner's record provide evidence that they are legally and professionally qualified to exercise the privileges granted them by the ASC?

Q-0122

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.45(b) Standard: Reappraisals

Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as

appropriate.

Interpretive Guidelines: §416.45(b)

The ASC's governing body must have a process reappraising the medical staff privileges granted to each practitioner. CMS recommends a reappraisal at least every 24 months. The reappraisal must include:

- Review of the practitioner's current credentials; and

- The practitioner's ASC-specific case record, including measures employed in the ASC's quality assurance/performance improvement program, such as emergency transfers to hospitals, post-surgical infection rates, other surgical complications, etc.

The ASC's governing body should use a similar process, including the recommendation of qualified medical personnel, for the periodic reappraisal as it used when initially granting privileges.

Based on the evidence, the ASC's governing body must decide whether to continue the practitioner's current privileges without change, or to amend those privileges by contracting or expanding them, or by withdrawal of the practitioner's privileges entirely.

The ASC must also reappraise a practitioner any time the practitioner seeks to perform procedures outside the scope of previously granted procedures.

The ASC should also develop triggers for reappraisal of privileges outside the periodic reappraisal schedule.

In the case of an ASC whose sole member of the governing body is also a member of the ASC's medical staff, it would be advisable to seek the recommendation of outside qualified medical personnel who review not only the physician's credentials, but also evidence of the physician's performance in the ASC.

Survey Procedures: §416.45(b)

- Does the ASC periodically reappraise all practitioners granted clinical privileges?

- Ask the ASC's leadership how it re-evaluates the professional qualifications of practitioners with privileges to practice in the ASC?

- Review the personnel records for all practitioners with privileges to practice in the ASC to determine whether they have been reappraised within the timeframe specific in the medical staff policy.

- Do the reappraisals include evidence that data on the practitioner's

practice within the ASC is considered along with the practitioner's credentials?

Q-0123

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.45(c) Standard: Other Practitioners

If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

Interpretive Guidelines: §416.45(c)

Patient care responsibilities (which may or may not include formal medical staff privileges, but excluding nursing care services) may be assigned to licensed practitioners not meeting the definition of physician in §1861(r) of the Act. "Physician" is defined in §1861(r) of the Social Security Act as:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry with respect to services legally authorized to be performed in the State; and
- Chiropractor with respect to treatment by manual manipulation of the spine (to correct subluxation diagnosed by x-ray).

When an ASC uses licensed practitioners to provide patient care, other than nursing care, the ASC's governing body must approve written policies and procedures that establish a system for overseeing and evaluating the quality of the clinical services provided by other practitioners. The policies must address:

- The specific types of clinical activities that each class of practitioner, e.g., Nurse Practitioner, Physician's Assistant, CRNA, will be eligible to perform. The ASC may not permit performance of any activities that are outside the licensed practitioner's permitted scope of practice under applicable State law;
- The process by which the ASC exercises oversight over each class of practitioner. Depending on the practitioner's scope of practice, physician supervision of the practitioner may be required; in other cases oversight through collaborative practice with a physician or some other means may suffice;
- The process and criteria for reviewing the qualifications of each individual practitioner before he/she is permitted to provide patient care; and

- The process, criteria and frequency for evaluating the performance in providing clinical services by practitioners other than physicians. Evaluations must take place at regular intervals specified in the ASC's policy.

Survey Procedures: §416.45(c)

- Determine whether the ASC uses licensed practitioners other than physicians to provide care, other than nursing care, within the ASC. If it does:

    - Ask to see the ASC's policy governing the oversight and evaluation of practitioners other than physicians. Does the policy address all required issues?

    - Review the personnel files for each licensed practitioner who is not a physician providing patient care in the ASC. Does each file contain evidence of the practitioner's qualifications, consistent with the ASC's policy? Does each file contain evidence of periodic evaluation of the practitioner's performance?

Q-0140

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.46 Condition for Coverage: Nursing Service

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

Interpretive Guidelines: §416.46

The ASC must ensure that the nursing service is directed under the leadership of an RN. The ASC must have documentation that it has designated an RN to direct nursing services.

There must be sufficient nursing staff with the appropriate qualifications to assure the nursing needs of all ASC patients are met. This implies that there is ongoing assessment of patients' needs for nursing care, and that identified needs are addressed. The number and types of nursing staff needed will depend on the volume and types of surgery the ASC performs.

Survey Procedures: §416.46

- Ask the ASC's leadership to identify the person responsible for the direction of nursing services within the ASC. Is that person an RN?

- Review the staffing available for patients undergoing surgery during the survey; is there sufficient staff to address each patient's nursing needs?

Do nursing staff have the appropriate qualifications for the tasks they are asked to perform?

Q-0141

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.46(a) Standard: Organization and Staffing

Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

Interpretive Guidelines: §416.46(a)

Every nurse in the ASC must have clearly delineated assigned responsibilities for providing nursing care to patients. These assignments must be in writing; job descriptions would suffice for a general articulation of the responsibilities for each nurse. Individual patient assignments on a given day must be documented clearly in the assignment sheet.

The ASC's nursing services must be consistent with recognized standards of practice. "Recognized standards of practice" means that the services provided are consistent with State laws governing nursing scope of practice, as well as with nationally recognized standards or guidelines for nursing care issued by organizations such as the American Nurses Association, the Association of Operating Room Nurses, etc.

An RN with specialized training or experience in emergency care must be available to provide emergency treatment whenever there is a patient in the ASC. "Available" means on the premises and sufficiently free from other duties that the nurse is able to respond rapidly to emergency situations. In accordance with the requirements at §416.44(d), the ASC must have personnel present who are trained in the use of the required emergency equipment specified at §416.44(c) and in cardiopulmonary resuscitation whenever there is a patient in the ASC. The RN(s) designated to provide emergency treatment must be able to use any of the required equipment, so long as such use falls within an RN's scope of practice. ASC's would be well advised to assure that the RN(s) designated to provide emergency treatment have training in advanced cardiac life support interventions.

Survey Procedures: §416.46(a)

- Are the general responsibilities for each ASC nurse for providing patient care clearly documented?

- Ask the nursing staff to explain what their duties for the day of the survey are; can they articulate clearly what their patient care responsibilities are?

- Ask the ASC to explain how it evaluates the nursing care provided in the ASC for conformance to acceptable standards of practice.

- Ask the ASC to identify the RN(s) who are available for emergency treatment. Is there documentation of their qualifications to provide emergency treatment? Do staff in the ASC know which RN(s) (as well as medical staff) to call when a patient develops an emergency?

- Ask the ASC for evidence that one or more RN(s) are readily available to provide emergency treatment. How do they assure that an RN can leave their current task to respond to the emergency without putting another patient at risk of harm?

Q-0160
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.47 Condition for Coverage: Medical Records

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

Interpretive Guidelines: §416.47

The ASC must have a complete, comprehensive and accurate medical record for each patient. Material required under other Conditions, such as the history and physical examination or documentation of allergies to drugs and biologicals required under §416.52, must be incorporated into the medical record in a timely fashion. The ASC must use the information contained in each medical record in order to assure that adequate care is delivered to each ASC patient. In accordance with the provisions of the Patients' Rights Condition at §416.50(g), the ASC must ensure the confidentiality of each patient's medical record.

Survey Procedures: §416.47

Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and ASC policy. If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.

Q-0161
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.47(a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

Interpretive Guidelines: §416.47(a)

The ASC must have a documented system that enables it to systematically develop a

unique medical record for each patient, permit timely access to the medical record to support the delivery of care, and to store records. Records may exist in hard copy, electronic format, or a combination of the two media.

The regulation does not prescribe how long a closed record is to be maintained by the ASC, but many States have laws governing retention of medical records.

Survey Procedures: §416.47(a)

- Review the ASC's medical record policy and interview the person responsible for the medical records to ascertain that the system is structured appropriately.

- If the ASC employs a fully or partially electronic medical record system, ask clinical personnel to demonstrate how they use the system in order to determine whether they are able to make entries and access needed information in order to support the provision of care.

- Determine that closed records are retained in accordance with applicable State law.

- Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and ASC policy. If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.

Q-0162

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.47(b) Standard: Form and Content of Record

The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification;
(2) Significant medical history and results of physical examination *(as applicable)*;
(3) Pre-operative diagnostic studies (entered before surgery), if performed;
(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;
(5) Any allergies and abnormal drug reactions;
(6) Entries related to anesthesia administration;
(7) Documentation of properly executed informed patient consent; and
(8) Discharge diagnosis.

Interpretive Guidelines: §416.47(b)

The medical record must contain all of the required elements listed in the regulation. Specifically:

• The identity of the patient must be clear through use of identifiers such as name, date of birth, social security number, etc.

• A medical history and physical assessment (H&P), completed *as applicable* and entered into the medical record in accordance with the requirements at §416.52, as well as the results of the pre-surgical assessments specified at §416.42 and §416.52.

• If pre-operative diagnostic studies were performed, they must be included in the medical record prior to the start of surgery.

• An operative report that describes the surgical techniques and findings. A pathologist's report on all tissues removed during surgery must also be included, unless the governing body has adopted a written policy exempting certain types of removed tissue from this requirement. Depending on the type of surgery performed in the ASC, tissue may or may not routinely be removed during surgery; no pathologist's report is required when no tissue has been removed. The governing body's policy on exemption should provide the clinical rationale supporting the exemption decision. For example, an ASC that performs cataract removal and implantation of an artificial lens might exempt from the pathologist's report requirement the ocular lens removed in routine procedures where there is no indication suggesting the presence of other disease for which a pathology analysis should be required. On the other hand, it generally would not be reasonable to exempt intestinal polyps removed during a colonoscopy, since a pathologist's analysis of the tissue would be required to confirm whether or not the polyp(s) were malignant growths.

• The patient's history of allergies or abnormal drug reactions prior to the surgery, as well as any allergies or abnormal drug reactions that occurred during or after the surgery prior to discharge.

• Information related to the administration of anesthesia during the procedure and the patient's recovery from anesthesia after the procedure.

• Documentation of a properly executed informed patient consent. A well-designed informed consent process would most likely include a discussion of the following elements:

    • A description of the proposed surgery, including the anesthesia to be used;

    • The indications for the proposed surgery;

    • Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could

include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity;

• Treatment alternatives, including the attendant material risks and benefits;

• Who will conduct the surgical intervention and administer the anesthesia;

• Whether physicians other than the operating practitioner will be performing important tasks related to the surgery. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines; and

• Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the ASC.

• Documentation of the patient's discharge diagnosis. The record should also include the patient's disposition, i.e., whether the patient was discharged to home (including to a nursing home for patients already resident in a nursing home at the time of surgery), or transfer to another healthcare facility, including emergent transfers to a hospital.

Survey Procedures: §416.47(b)

• Evaluate the sample of open and closed records selected for review to determine whether they contain all of the required elements. For open records of patients whose surgery has not yet begun, focus on the elements that must be present before surgery, e.g., H&P *(as applicable)*, immediate pre-surgical assessment, informed consent, etc. The absence of any required element must be cited as standard-level noncompliance. The absence of a number of elements from a number of medical records might warrant citation of condition-level noncompliance. Likewise the absence of one element from a number of medical records – e.g., lack of informed consent to surgery – should warrant citation of condition-level noncompliance.

Ask the ASC's leadership if the ASC removes tissue during surgery and, if so, does it exempt any or all classes of tissue removed from the requirement for analysis by a pathologist? If yes, ask to see the policy and its rationale, to determine whether it was adopted by the governing body and whether the clinical rationale for the exemption is reasonable.

Q-0180

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48 Condition for Coverage: Pharmaceutical Services

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

Interpretive Guidelines: §416.48

Drugs and biologicals used within the ASC must be provided safely and in an effective manner, consistent with generally accepted professional standards of pharmaceutical practice and with the requirements specified in the Standards within this Condition.

The ASC must designate a specific licensed healthcare professional to provide direction to the ASC's pharmaceutical service. That individual must be routinely present when the ASC is open for business, but continuous presence is not required, particularly when the ASC is open for longer periods of time to accommodate the recovery of patients for up to 24 hours. Ideally the ASC should have available a pharmacist who provides oversight or consultation on the ASC's pharmaceutical services, but this is not required by the regulation, unless the ASC is performing activities which under State law may only be performed by a licensed pharmacist.

Survey Procedures: §416.48

- Ask the ASC's leadership for evidence that a qualified individual has been designated to direct pharmaceutical services in the ASC.

- Ask how often and for how long this individual is on-site at the ASC. Determine whether there is any documentation indicating that the individual is providing active direction and oversight to the program.

Q-0181
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

Drugs must be prepared and administered according to established policies and acceptable standards of practice

Interpretive Guidelines: §416.48(a)

Drugs and biologicals used within the ASC must be administered to patients in accordance with formal policies the ASC has adopted, and those policies and the ASC's actual practices must conform to acceptable standards of practice for medication administration.

"**Accepted professional practice**" and **"acceptable standards of practice"** mean that drugs and biologicals are handled and provided in the ASC in accordance with applicable State and Federal laws as well as with standards established by organizations with nationally recognized expertise in the clinical use of drugs and biologicals. This would

include organizations such as the National Association of Boards of Pharmacy, the Institute for Safe Medication Practices, the American Society of Health-System Pharmacists, etc.

The ASC must have policies and procedures designed to promote medication administration consistent with acceptable standards of practice. The policies and procedures should address issues including, but not limited to:

- A physician or other qualified member of the medical staff acting within their scope of practice must issue an order for all drugs or biologicals administered in the ASC. The administration of the drugs or biologicals must be by, or under the supervision of, nursing or other personnel in accordance with applicable laws, standards of practice and the ASC's policies.

- Following the manufacturer's label, including storing drugs and biologicals as directed; disposing of expired medications in a timely manner; using single-dose vials of medication for one ASC patient only; etc.
- Avoiding preparation of medications too far in advance of their use. For example, while it may appear efficient to pre-draw the evening before all medications that will be used for surgeries scheduled the following day, this practice may, depending on the particular drug or biological, promote loss of integrity, stability or security of the medication.

- Any pre-filled syringes must be initialed by the person who draws it, dated and timed to indicate when they were drawn, and labeled as to both content and expiration date.

- Employing standard infection control practices when using injectable medications.

There must be records of receipt and disposition of all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the ASC uses any such scheduled drugs. The ASC's policies and procedures should also address the following:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.

- Records to trace the movement of scheduled drugs throughout the ASC.

- The licensed health care professional who has been designated responsible for the ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

- The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

- The ASC's system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion?

Survey Procedures: §416.48(a)

- Is there evidence in the medical records reviewed that there is an order, signed by a physician or other qualified practitioner, for every drug or biological administered to the patient?
- Are drugs or biologicals administered only by nurses or other qualified individuals, or under the supervision of nurses or other qualified individuals, as permitted under Federal or State law and the ASC's policy?

- Determine whether medications are properly labeled, stored, and have not expired.

- Using the infection control survey tool, determine whether the ASC employs safe injection practices.

- If the ASC uses scheduled drugs:

    - Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.

    - Review the records to determine that they trace the movement of scheduled drugs throughout the ASC.

    - Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction or return to the manufacturer. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

    - Determine if the licensed health care professional who is in charge of the

ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.

- Is the ASC's system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?

- Determine if facility policy and procedures minimize scheduled drug diversion.

Q-0182

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

Interpretive Guidelines: §416.48(a)(1)

Every adverse reaction to a drug or biological that a patient experiences while in the ASC must be reported promptly to the physician on the ASC's medical staff who is responsible for that patient. This permits that physician to assess the patient in a timely manner and determine whether additional treatment is required in order to counteract the adverse reaction.

All adverse drug reactions experienced by patients while in the ASC must be documented in the patient's medical record.

The ASC's policies and procedures must incorporate these requirements and ASC staff must be aware of and comply with them.

Survey Procedures: §416.48(a)(1)

- Interview clinical staff to ask them what steps they would take if a patient experiences an adverse reaction to a drug? Are staff aware of the requirement to promptly report this information to the physician on the ASC's medical staff who is responsible for the patient?

- Look for documentation of adverse drug reactions in the sample of records selected for review. If no adverse drug reactions are noted, ask ASC staff whether they recall any patients having adverse drug reactions, and if so, whether they could pull a medical record containing documentation of an adverse drug reaction.

- Determine whether the ASC's policies and procedures address adverse drug

reactions and are consistent with the regulatory requirements.

Q-0183
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

(2) Blood and blood products must be administered only by physicians or registered nurses.

Interpretive Guidelines: §416.48(a)(2)

If the ASC ever administers blood or blood products to patients, it may permit only a physician on the ASC's medical staff or an RN working in the ASC to administer blood and blood products. The ASC's policies and procedures must specifically address this requirement, unless the ASC does not keep blood or blood products on hand and never administers such products to ASC patients.

Survey Procedures: §416.48(a)(2)

- Determine whether the ASC administers blood or blood products to patients. If yes,
    - Determine from the record review whether anyone other than a physician on the ASC's medical staff or an ASC RN administered the blood or blood product.
    - Determine whether the ASC's policies specifically restrict administration of blood and blood products to a physician or RN.

Q-0184
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.

Interpretive Guidelines: §416.48(a)(3)

Orders for drugs and biologicals that are transmitted as oral, spoken communications between the prescribing physician and the ASC's nursing staff, delivered either face-to-face or via telephone, commonly called "verbal orders," must be followed by a written order that is signed by the prescribing physician.

CMS expects ASC policies and procedures for verbal orders to include a read-back and verification process whereby the nurse receiving the order repeats it back to the prescribing physician, who verifies that it is correct. When administering a drug or biological per a verbal order, the nurse should include in the medical record entry

covering the administration of the drug or biological a note that it was prescribed orally, indicating the name of the prescribing physician.

The prescribing physician must sign, date, and time the written order in the patient's medical record confirming the verbal order. This should be done as soon as possible after the verbal order is issued.

In the ASC setting medications prescribed for patients in recovery present a particular area of vulnerability in terms of the potential failure to follow-up a verbal order with a written order signed by the prescribing physician. Careful attention must be given to compliance with the regulatory requirement for medications administered during recovery room.

Survey Procedures: §416.48(a)(3)

- Does the ASC have policies and procedures addressing verbal orders? Does it require the prescribing practitioner to sign, date, and time a written order as soon as possible after issuing the verbal order?

- Do the ASC's policies and procedures for verbal orders include a "read back and verify" process where the nurse who receives the order repeats it back to the prescribing physician to verify that the order was understood accurately?

- Ask ASC nursing staff how they handle verbal orders. Does their practice conform to the regulatory requirements? Do they use a read-back and verify process?

- Is there evidence in the medical records reviewed that each verbal order was followed by a written order signed by the prescribing physician?

Q-0200
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.49 Condition for Coverage: Laboratory and Radiologic Services

Interpretive Guidelines: §416.49(a)

Lack of substantial compliance with either the laboratory or the radiologic standard within this condition could provide a basis for citing a condition-level deficiency.

Q-0201
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.49(a) Standard: Laboratory Services

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must

have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.

Interpretive Guidelines: §416.49(a)

ASC policies and procedures should list the kinds of laboratory services that are provided directly by the facility, and services that are provided through a contractual agreement. Review the contractual agreements and determine if the referral laboratory is a CLIA-approved laboratory. The ASC procedures must include the following:

- A well-defined arrangement (need not be contractual) with outside services;
- Laboratory services that are provided by the ASC;
- Routine procedures for requesting lab tests; and
- Language that requires the incorporation of lab/radiological reports into patient records.

When laboratory tests are performed prior to admission, the results should be readily available to the attending physician in the ASC.

Q-0202

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b) Standard: Radiologic Services.

(1) Radiologic services may only be provided when integral to procedures offered by the ASC …

Interpretive Guidelines: §416.49(b)(1)

An ASC may only provide radiological services as an integral part of the surgical procedures it performs. Radiological services integral to the procedure itself are those imaging services performed immediately before, during or after the procedure that are medically necessary to the completion of the procedure.

If the ASC does not provide these radiological services directly, i.e., utilizing its own staff, then it must obtain them via a contract or other formal arrangement.

Survey Procedures: §416.49(b)(1)

- Does the ASC provide, either directly or under arrangement, radiologic services? If yes, verify that it performs only those radiologic services that are integral to its surgical services?

Q-0203
(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b)(1) [Radiologic services…]

. . . must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2) of this chapter.

Interpretive Guidelines §416.49(b)(1)

The scope and complexity of radiological services provided within the ASC, either directly or under arrangement, as an integral part of the ASC's surgical services must be specified in writing and approved by the governing body. The ASC must also ensure that the provision of radiological services in the ASC complies with the hospital radiologic services requirements at § 482.26(b), (c)(2), and (d)(2), regardless of whether the service is provided directly by the ASC or under arrangement.

The interpretive guidelines for § 482.26(b), (c)(2), and (d)(2) in Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals of the State Operations Manual, provide the following guidance in determining compliance:

§482.26(b) Standard: Safety for Patients and Personnel

The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

Interpretive Guidelines §482.26(b)

The hospital must adopt and implement policies and procedures that provide safety for patients and personnel.

Survey Procedures §482.26(b)

Observe locations where radiological services are provided. Are they safe for patients and personnel? Are any hazards to patients or personnel observed?

§482.26(b)(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials.

Interpretive Guidelines §482.26(b)(1)

The hospital policies must contain safety standards for at least:

- Adequate shielding for patients, personnel and facilities;

- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the hospital;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;
- Proper storage of radiation monitoring badges when not in use;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.
- Methods of identifying pregnant patients.

The hospital must implement and ensure compliance with its established safety standards.

Survey Procedures §482.26(b)(1)

- Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the hospital.
- Verify that hazardous materials are stored properly in a safe manner.
- Observe areas where testing is done for violations in safety precautions.

§482.26(b)(2) Periodic inspection of equipment must be made and hazards identified must be properly corrected.

Interpretive Guidelines §482.26(b)(2)

The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner. The hospital must ensure that equipment is inspected in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and hospital policy. The hospital must have a system in place, qualified employees or contracts, to correct hazards. The hospital must be able to demonstrate current inspection and proper correction of all hazards.

Survey Procedures §482.26(b)(2)

- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines and hospital policy.

- Determine that any problems identified are properly corrected in a timely manner.

§482.26(b)(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Interpretive Guidelines §482.26(b)(3)

The requirement that "radiation workers must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure" would include radiological services personnel, as well as, other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include personnel such as certain nursing and maintenance staff.

Survey Procedures §482.26(b)(3)

- Verify that the hospital requires periodic checks on all radiology personnel and any other hospital staff exposed to radiation and that the personnel are knowledgeable about radiation exposure for month, year, and cumulative/entire working life.

- Observe that appropriate staff have a radiation-detecting device and that they appropriately wear their radiation detecting device.

- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.

§482.26(b)(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

Survey Procedures §482.26(b)(4)

Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges and to practitioners outside the hospital who have been authorized by the medical staff and the governing body to order radiological services, consistent with State law.

§482.26(c)(2) Only personnel designated as qualified by the medical staff may use

the radiologic equipment and administer procedures.

Interpretive Guidelines §482.26(c)(2)

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

Survey Procedures §482.26(c)(2)

Determine which staff are using differing pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine they meet the qualifications established by the medical staff for the tasks they perform.

§482.26(d)(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts

(ii) Films, scans, and other image records, as appropriate.

Interpretive Guidelines §482.26(d)(2)

Patient radiology records are a type of patient medical record. The hospital must maintain radiology records in compliance with the medical records CoP and this CoP. Medical records, including radiology records, must be maintained for 5 years.

Survey Procedures §482.26(d)(2)

- Verify that the hospital maintains records for at least 5 years.

- Verify that radiology records are maintained in the manner required by the Medical Records…." [CfC].

Survey Procedures: §416.49(b)(1)

- If the ASC provides radiologic services as an integral part of surgical procedures, does it comply with the requirements of §482.26(b), (c)(2), and (d)(2) in its provision of those services, using the hospital radiologic services interpretive guidelines cited above?

- Interview the individual designated responsible for assuring compliance with this CfC and review related documentation to assess how these responsibilities have been implemented in the ASC. For example, is there evidence that this individual monitors and/or oversees the monitoring of compliance with all of the requirements in §482.26(b), (c)(2), and (d)(2)? What steps are available to this individual to remedy the situation if there is evidence of noncompliance with any of the requirements?

Q-0204
(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b)(2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.

Interpretive Guidelines: §416.49(b)(2)

If the ASC provides radiologic services, the ASC's governing body must appoint an individual who has appropriate qualifications, in accordance with State law and Federal regulations, to provide oversight of these services. The appointed individual is responsible for assuring the ASC's compliance with §§482.26(b), (c)(2), and (d)(2). In order to assure compliance with these requirements the individual is expected to be qualified, through training and/or experience, to oversee areas including, but not limited to: use of safety precautions (shielding, and appropriate storage, use and disposal of radioactive materials) against radiation hazards; regular equipment inspection and hazard correction; regular review of radiation worker radiation exposure; assuring use of radiologic equipment only by qualified personnel; and maintenance of imaging results or records. The person appointed to oversee radiologic services could be someone already working in the ASC who is qualified in accordance with State law and Federal regulations. Under the medical staff credentialing and privileging requirements at §416.45, the ASC's governing body will continue to be required to ensure that the operating surgeon is competent both to perform the surgical procedures for which privileges have been issued by the ASC and to appropriately and safely use the imaging modalit(ies) that are integral to the procedures s/he performs.

Survey Procedures: §416.49(b)(2)

- Can the ASC demonstrate that the individual responsible for assuring all radiologic services are provided in accordance with the requirements of this section:

    - Is qualified for this role in accordance with State and/or Federal law and regulations and ASC policies?
    - Was appointed by the ASC's governing body?

Q-0219
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50 Condition for Coverage - Patient Rights

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a

place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

Interpretive Guidelines: §416.50

The ASC must inform each of its patients, or the patient's representative or surrogate in the case of minor patients or other situations where there is a designated representative for the patient, of their rights as an ASC patient. Further, all of the ASC's policies, procedures and actions must be consistent with the protection of the patients' rights articulated in this Condition. Further, the ASC must actively promote the patient's exercise of their rights.

In addition, the ASC must ensure that the written notice of patient rights is posted in one or more places where it is likely to be seen by patients waiting for treatment, or the patient's representative or surrogate, if applicable. Such areas include, but are not limited to, waiting rooms or pre-operative preparation areas where patients are awaiting care. Notices must be posted in at least one area. Whether the ASC must post more than one notice depends on the size and physical layout of the areas where notices are posted. The determining factor is whether the notice(s) are posted in a manner that all patients (or their representatives or surrogates, as applicable) are likely to see the notice.

The patient's representative or surrogate is an individual designated by the patient, in accordance with applicable State law, to make health care decisions on behalf of the individual or to otherwise assist the patient during his/her stay in the ASC. Designation may be in writing, as in an advance directive or medical power of attorney, or may be oral (verbal). Written designation may occur before the patient presents to the ASC, or during the ASC registration process. Oral designation may take place at any time during the patient's visit in the ASC. The patient's representative or surrogate includes, but is not limited to, an individual who could be a family member or friend who accompanies the patient. Depending on the designation the patient has made, the patient's representative or surrogate may make all health care decisions for the patient during his/her ASC visit, or may act in a more limited role, for example, as a liaison between the patient and the ASC to help the patient communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the ASC staff. If a patient is unable to fully communicate directly with the ASC staff, then the ASC may give patient rights information to the patient's representative or surrogate.

Survey Procedures: §416.50

When there is a team surveying the ASC, survey of the Patients' Rights Condition should be coordinated by one surveyor. However, each surveyor, as he or she conducts his/her survey assignments, should assess the ASC's compliance with the Patient's Rights regulatory requirements. It is particularly important for the surveyor who will be following one or more patients from the start of their case to discharge to be observing how the ASC's actions protect and promote those patients' exercise of their rights.

- Determine whether the ASC provides patients (or their representatives or

surrogates, as applicable), with notice of their rights, consistent with the standards under this condition.

- Determine whether the ASC promotes the patients' exercise of their rights (or their representatives or surrogates, as applicable), consistent with the standards under this condition.

Review posted notices to determine if they contain the same information as the individual written notice provided to patients or their representatives/surrogates, as required under §416.50(a). Deficiencies related to posting of the notice are to be cited using tag -Q0219.

Q-0220

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50…. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

Interpretive Guidelines: §416.50 (standard-level citation only)

Since the condition concerning posting the written notice does not have a counterpart in a standard within the patient rights condition, a second tag is provided for this portion of the condition for citations at the standard level. Deficiencies related solely to posting of the notice must be cited at the standard level, using tag Q-0220. The condition-level tag, Q-0219, must be cited whenever the manner and degree of noncompliance on the part of an ASC represents substantial noncompliance.

Survey Procedures: §416.50(standard-level citation only)

Observe waiting rooms and pre-operative areas where patients await care to see if notice of patient rights is posted in a manner where all patients awaiting care are likely to see a notice. Ensure that the notices are posted in conspicuous locations in the waiting rooms, pre-operative preparation areas, recovery rooms, or other common areas. If only one notice is posted, verify that it is conspicuously located in an area use by every ASC patient. Deficiencies related to posting of the notice are to be cited using tag -Q0219.

Q-0221

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(a) Standard: Notice of Rights

An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the

Web site for the Office of the Medicare Beneficiary Ombudsman.

Interpretive Guidelines: §416.50(a)

The ASC must inform each patient, or the patient's representative or surrogate of the patient's rights. This notice must be provided both verbally and in writing prior to the start of the surgical procedure, i.e., prior to the patient's movement out of the pre-operative area, and, if applicable, before the patient is medicated with a drug(s) that suppresses the patient's consciousness. It is not acceptable for the ASC to provide the notice when the patient has already been moved into the operating room (including procedure room) or has been medicated in such a manner that he or she is not able to follow or remember the provision of notice.

This regulation does not require that in every instance notice be delivered just prior to the start of the surgical procedure. Instead, the regulation indicates the latest acceptable time for delivery of the notice. It would be acceptable for the ASC to mail or e-mail the notice of patient rights in advance of the date of the scheduled procedure, or at the time the patient appears in the registration area on the date of the procedure. CMS recommends that ASCs provide patients notice of their rights as soon as possible after the procedure is scheduled, but so long as notice is provided prior to the start of the surgical procedure, the ASC is in compliance with the regulation.

Notice must be provided regardless of the type of procedure scheduled to be performed.

The regulation does not require a specific form or wording for the written notice, so it is acceptable for the ASC to develop a generic, pre-printed notice for use with all of its patients, as long as the notice includes all of the patient rights established under the regulation.

The notice must include the address and telephone number of the appropriate State agency to which patients may report complaints about the ASC. If available, an e-mail or web address for submission of complaints to the State agency should also be provided.

The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html

Patients who are Medicare beneficiaries, or their representative or surrogates, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

The notice must:

- Address all of the patient's rights under this Condition.

- Be provided and explained in a language and manner that the patient or the

patient's representative or surrogate understands, including patients who do not speak English or with limited communication skills. The patient has the choice of using an interpreter of his or her own, or one supplied by the ASC. A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the ASC to the patient. In following translation practices, CMS recommends, but does not require, that a written translation be provided in languages that non-English speaking patients can read, particularly for languages that are most commonly used by non-English-speaking patients of the ASC. We note that there are many hundreds of languages (not all written) that are used by one or more residents of the United State, but that in most geographic areas the most common non-English language generally is Spanish. We note there are other applicable legal requirements, most notably, those under title VI of the Civil Rights Act of 1964. The Department of Health and Human Services' (HHS) guidance related to Title VI of the Civil Rights Act of 1964, ''Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons'' (68 FR 47311, Aug. 8, 2003) applies to those entities that receive federal financial assistance from HHS, including ASCs. This guidance may assist ASCs in ensuring that patient rights information is provided in a language and manner the patient understands. The regulation at §416.50(a) is compatible with guidance on Title VI.

Survey Procedures: §416.50(a)

- Determine what the ASC's policy and procedures are for providing all patients and/or their representatives or surrogates notice of their rights prior to the start of the surgical procedure. Are the policies and procedures consistent with the regulatory requirements?

- Determine whether the information provided in the written notice to the patients and/or their representatives or surrogates by the ASC is complete and accurate:

o Does the notice address all of the patients' rights listed in this Condition?

o Does the notice provide the required information about where to file complaints or how to contact the Medicare Ombudsman?

- Is the staff who are responsible for advising patients of their rights aware of the ASC's policies and procedures for providing such notice, including to those patients with special communication needs?

- Review records, interview staff, and observe staff/patient interaction to examine how the ASC communicates information about patient rights to diverse patients, including patients who need assistive devices or translation services.

- Does the ASC provide all patients with verbal and written notice of their rights prior to the start of the surgical procedure?

- Does the ASC have a significant number of patients with limited English proficiency? If so, are there written notice materials available for patients who have a primary language other than English? If not, does the ASC have translators available to provide verbal notice of their rights to ASC patients?

- Ask patients to tell you how, when and what the ASC has told them about their rights.

Q-0222

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(a) Standard: Notice of rights

(1)[…] In addition, the ASC must –

(i) Post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

Interpretive Guidelines: §416.50(a)(1)(i)

The ASC must ensure that a written notice of patient rights is posted in one or more places where they are likely to be noticed. This would include waiting rooms, recovery rooms, or any other areas where patients and/or their representatives are likely to be. Notices must be posted in at least one area. Posting in more than one area increases the likelihood that patients will see the notice, but an ASC may post only one notice and comply with the requirement, so long as the notice is posted in an area used by every ASC patient and where it is likely to be noticed.

The notice must include the name, address, and telephone number of a representative in the State survey agency to whom patients and/or their representatives can report complaints. Because there can be staff turnover in the State survey agency, creating a burden for both States and ASCs to keep current the names of State staff, it is sufficient if the notice provides the title of the individual in the State survey agency to whom complaints may be reported, as well as the address and telephone number.

The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html

Patients who are Medicare beneficiaries, or their representative, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

Survey Procedures: §416.50(a)(1)(i)

- Observe waiting rooms, recovery rooms, and other common areas used by patients to see if one or more notices of patient rights are posted. Ensure that the notices are posted in conspicuous locations in the waiting rooms, recovery rooms, or other common areas. If only one notice is posted, verify that it is conspicuously located in an area used by every ASC patient.

- Observe notices to see that each notice contains all required information.

Q-0223

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(b) Standard: Disclosure of physician financial interest or ownership

The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.

Interpretive Guidelines: §416.50(b)

An ASC that has physician owners or investors must provide written notice to the patient, the patient's representative or surrogate, prior to the start of the surgical procedure, that the ASC has physician-owners or physicians with a financial interest in the ASC. CMS considers the disclosure of physician financial interest or ownership to be part of the overall "patient rights information" that is now required to be given prior to the start of the procedure. 42 CFR Part 420 provides definitions and requirements concerning ownership and control of Medicare-participating providers and suppliers. Surveyors are not expected to have expert knowledge of what constitutes ownership and control, but ASCs are required to comply with the provisions of Part 420. ASCs that meet the physician ownership and control threshold specified in 42 CFR Part 420 must disclose their physician ownership to patients and provide them with a list of physicians who have a financial interest or ownership in the ASC. The intent of this disclosure requirement is to assist the patient in making an informed decision about his or her care by making the patient, or the patient's representative or surrogate, aware when physicians who refer their patients to the ASC for procedures, or physicians who perform procedures in an ASC also have an ownership or financial interest in the ASC.

The written notice must disclose, in a manner designed to be understood by all patients,

that physicians have an ownership or financial interest in the ASC. Information should be provided in a manner that is not only technically correct, but also easily understood by persons not familiar with financial statements, legal documents or technical language. The ASC should also be aware of the age and the cognitive abilities of its patients in developing its written notice. (72 FR 50475, August 31, 2007)

Survey Procedures: §416.50(b)

- Ask the ASC whether it is has reported in accordance with 42 CFR Part 420 to the Medicare program whether the ASC has any physicians with ownership/financial interests. (Surveyors are not required to make an independent determination regarding whether an ASC has physicians with ownership or financial interests.) If the answer is yes, then the ASC is required to comply with the requirement for disclosure to patients. If the ASC's response is no, then the ASC has no disclosure requirement and the surveyor does not have to investigate further.

- If the ASC indicates it has physicians with ownership/financial interests in the ASC:

    - Does the ASC have policies and procedures in place to make the required disclosures to patients? Are the policies and procedures consistent with the regulatory requirements?

    - Does the ASC provide a written notice of disclosure to all patients prior to the start of the surgical procedure, including a list of physicians with financial interests or ownership in the ASC?

- Interview ASC staff to assess their knowledge and understanding of the physician ownership notice requirements, including the ASC's process for delivering the notice.

- Interview patients to ask them whether they were aware that the ASC has physician owners/investors. Ask them if they recall getting a written notice about this prior to the start of their surgical procedure.

Q-0224

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(c) Standard: Advance Directives

The ASC must comply with the following requirements:

(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(2) Inform the patient or, as appropriate, the patient's representative of the patient's

rights to make informed decisions regarding the patient's care.

(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

Interpretive Guidelines: §416.50(c)

Information on Advance Directives

An advance directive is a written instruction, such as a living will or durable power of attorney for healthcare, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of healthcare when the individual who has issued the directive is incapacitated. (See 42 CFR 489.100.)

Each ASC patient has the right to formulate an advance directive consistent with applicable State law and to have ASC staff implement and comply with the advance directive, subject to the ASC's limitations on the basis of conscience. To the degree permitted by State law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process.

The facility must provide the patient or the patient's representative, as appropriate, the following information in writing, prior to the start of the surgical procedure:

- Information on the ASC's policies on advance directives;
- A description of the applicable State health and safety laws. (Note that CMS does not determine whether this description is accurate. State Survey Agencies are responsible for making this accuracy determination.); and
- If requested, official State advance directive forms, if such exist.

The ASC must include in the information concerning its advance directive policies a clear and precise statement of limitation if the ASC cannot implement an advance directive on the basis of conscience or any other specific reason that is permitted under State law. A blanket statement of refusal by the ASC to comply with any patient advance directives is not permissible. However, if and to the extent permitted under State law, the ASC may decline to implement elements of an advance directive on the basis of conscience or any other reason permitted under State law if it includes in the information concerning its advance directive policies a clear and precise statement of limitation. A statement of limitation must:

- Clarify any differences between ASC-wide conscience objections and those that may be raised by individual ASC staff;
- Identify the state legal authority permitting such objection; and
- Describe the range of medical conditions and procedures affected by the objection

For example, the ASC's notice of limitation could, if permitted by State law, indicate that it would always attempt to resuscitate a patient and transfer that patient to a hospital in the event of deterioration.

The patient may wish to delegate his/her right to make informed decisions to another person, even though the patient is not incapacitated. To the extent permitted by State law, the ASC must respect such delegation. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney, or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative or surrogate, so that informed healthcare decisions can be made for the patient. However, as soon as the patient is able to be informed of his or her rights, the ASC should also provide that information to the patient.

The right to make informed decisions presumes that the patient, or the patient's representative or surrogate, has been provided information about the patient's health status, diagnosis and prognosis. It includes providing consent to the surgical procedure(s) to be performed in the ASC. The patient, or the patient's representative or surrogate, must receive adequate information, provided in a manner that the patient or the patient's representative or surrogate can understand, to assure that the patient can effectively exercise the right to make informed decisions about care in the ASC. In many cases, the informed consent may take place in a physician office outside the ASC and prior to the patient's visit to the ASC. Nevertheless, the ASC is responsible for ensuring an informed process is in place for each patient. (See discussion of fully informing the patient under §416.50(e)(iii).)

Documentation of Advance Directives

The ASC must document in the patient's current medical record, i.e., the record for the current ASC visit, whether or not the patient has executed an advance directive. This documentation must be placed in a prominent part of the medical record where it will be readily noticeable by any ASC staff providing clinical services to the patient. The documentation requirement applies, even if the ASC is unable to comply with the patient's advance directive on the basis of conscience or a State law limitation.

If the patient with an advance directive is transferred from the ASC to another healthcare facility, e.g., if there is an emergency transfer to a hospital, the ASC must ensure that a copy of the patient's advance directive is provided with the medical record when the patient is transferred.

The ASC should provide education to its staff concerning the facility's policies and procedures on advance directives.

Survey Procedures: §416.50(c)

- Review the ASC's policies and procedures related to the advance directive requirements. Do they conform to the regulatory requirements?

- Ask to see a copy of the written notice of the ASC's advance directive policies and applicable State law. Does it contain all required information? If there is a statement of limitations based on conscience or State law, does it include all required information?

- If the State has an official advance directive form, ask the ASC to demonstrate how it provides these forms upon request to patients.

- Ask the ASC how it documents that required advance directive information is provided to the patient prior to the start of the surgical procedure. Review each record in the survey sample to determine if there is evidence that the information was provided to the patient or the patient's representative prior to the start of the surgical procedure.
- Review each record in the survey sample to determine if advance directive information was provided prior to the start of the surgical procedure.

- Does the ASC advise patients, or the patient's representative or surrogate, of their right to make informed decisions about their care in the ASC?

- Review each record in the survey sample to determine if information is prominently displayed as to whether or not there is an advance directive in effect for the patient. Is the information displayed in a manner such that patients with advance directives can be readily distinguished from patients without an advance directive?

- Determine to what extent the ASC educates its staff regarding advance directives and promoting informed decisions. Does the ASC have a training class or any educational materials available for the staff regarding advance directives and informed patient decision-making? Interview staff to determine their knowledge of the advance directives of the patients in their care.

Q-0225

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(d) Standard: Submission and investigation of grievances

The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:

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(3) The grievance process must specify timeframes for review of the grievance and

the provisions of a response.

(4) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.

(5) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.

Interpretive Guidelines: §§416.50(d)(4), (5), & (6)

What is a Grievance?

A "patient grievance" is a formal or informal written or verbal complaint that is made to the ASC by a patient or a patient's representative or surrogate, regarding a patient's care (when such complaint is not resolved at the time of the complaint by the staff present), abuse, neglect, or ASC compliance issues.

- A complaint from someone other than a patient or a patient's representative or surrogate is not a grievance.

- A complaint that is presented to the ASC's staff and resolved at that time is not considered a grievance; the grievance process requirements do not apply to such complaints. For example, a complaint that discharge instructions are unclear may be resolved relatively quickly before the patient is discharged, and would not usually be considered a "grievance."

If a patient care complaint cannot be resolved at the time of the complaint by the staff present, is postponed for later resolution, is referred to other staff for later resolution, requires an investigation, and/or requires additional actions for resolution, the complaint is then considered a grievance for purposes of these requirements.

Billing issues are not usually considered grievances for the purposes of this grievance requirement.

Although complaints may be both written and verbal, a written complaint is always considered a grievance. This includes written complaints from a current patient, a released/discharged patient, or a patient's representative or surrogate regarding the patient care provided, abuse or neglect, or the ASC's compliance with the CfCs. For the purposes of this requirement, an email or fax is considered written.

Information obtained from patient satisfaction surveys conducted by the ASC usually is not considered a grievance. However, if an identified patient writes or attaches a written complaint on the survey and requests resolution, the complaint must be treated as a grievance. If an identified patient writes or attaches a complaint to the survey, but does

not request resolution, the ASC should treat this as a grievance if the ASC would usually treat such a complaint as a grievance.

Patient complaints that are considered grievances also include situations where a patient or a patient's representative or surrogate telephones the ASC with a complaint regarding the patient's care or with an allegation of abuse or neglect, or a failure of the ASC to comply with one or more of the CfCs.

Whenever the patient or the patient's representative or surrogate requests that his or her complaint be handled as a formal complaint or grievance, or when the patient requests a response from the ASC, the complaint is considered a grievance and all the grievance requirements apply.

Grievance Process

The ASC must have an established procedure in place for documenting the existence, submission, investigation, and disposition of a grievance.

As part of its obligation to notify patients of their rights, the ASC must inform the patient and/or the patient's representative or surrogate of the ASC's grievance process, including how to file a grievance.

All grievances submitted to any ASC staff member, whether verbally or in writing, must be reported by the staff to an ASC official who has authority to address grievances. The ASC's grievance policies and procedures must identify the person(s) in the ASC who have the authority to respond to grievances. The ASC is expected to educate staff on their obligation to report all grievances, including whom they should report the grievance to.

All grievances must be investigated, but the regulation stresses this in particular for grievances related to treatment or care that the ASC provided or allegedly failed to provide. In its investigation the ASC should not only respond to the substance of the grievance, but should also use the grievance to determine if there are systemic problems indicated by the grievance that require resolution. An ASC would be well-advised to integrate its grievance process into its overall quality assessment and performance improvement program.

The ASC's grievance process must include a timeframe for the completion of the ASC's review of the grievance allegations, as well as for the ASC to provide a response to the person filing the grievance. The timeframe must be reasonable, i.e., allowing the ASC sufficient but not excessive time to conduct its review and issue its response. CMS does not mandate a particular timeframe. The application of the ASC's timeframe begins with the date of the receipt of the grievance by the ASC.

The ASC must document for each grievance how it was addressed. The ASC must also notify the patient or the patient's representative or surrogate, in writing, of the ASC's decision regarding each grievance.

The ASC may use additional methods to resolve a grievance, such as meeting with the patient's family. There are no restrictions on the ASC's use of additional effective methods to handle a patient's grievance. However, in all cases, the ASC must provide a written notice of its decision on each patient's grievance. The written notice must include the name of an ASC contact person, the steps the ASC took to investigate the grievance, the results of the grievance process, and the date the process was completed.

When a patient communicates a grievance to the ASC via email, the ASC may respond to the patient via email, pursuant to the ASC's policy. (Some ASC may have policies prohibiting communication to patients via email.) If the patient requests a response via email, the ASC may respond via email. If the email response contains the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the process was completed, the email meets the requirements for a written response.
In its written response to any grievance, the ASC is not required to include statements that could be used in a legal action against the ASC, but the ASC should provide adequate information to address the specific grievance. A form letter with generic statements about grievance process steps and results is not acceptable.

Survey Procedures: §§416.50(d)(4)(5), & (6):

- Determine whether the ASC has a written policy addressing the grievance process. Does the process specifically address how grievances are documented, how they are to be submitted, how they are to be investigated, and how the findings are to be used to dispose of the grievance? Does the policy comply with the regulatory requirements concerning reporting of grievances,, timeframe, and notice of disposition?

- Ask the ASC how many grievances it received during the past year. Ask how it documents the existence of grievances. Ask what the disposition was of grievances processed during that period. Ask to see a sample of grievance files. If this is a complaint survey concerning a grievance, ask to see grievances submitted at the time of the grievance that triggered the complaint survey.

- Review a sample of grievance files to determine if grievances are properly documented and handled in accordance with the ASC's policy and the regulatory requirements.

- Interview staff to see if staff is aware of the ASC's grievance policies. Do staff know the difference between a complaint handled on the spot and a grievance?

- Interview patients and/or representatives or surrogates to determine if they know how to file a grievance and who to contact if they have a complaint/grievance.

- Interview staff and patients to see how staff and patients are educated regarding to whom grievances and allegations should be reported.

Q-0226
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(d) Standard: Submission and investigation of grievances

…. The following criteria must be met:

(1) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(2) All allegations must be immediately reported to a person in authority in the ASC.

(3) Only substantiated allegations must be reported to the State authority or the local authority, or both.

Interpretive Guidelines: §§416.50(d)(1), (2), & (3)

Grievances making allegations related to mistreatment; neglect; verbal, mental, sexual or physical abuse; or other serious allegations of harm must be fully documented. This means that all pertinent details of the allegation must be recorded and retained in the ASC's files. Documentation of the allegation should include, at a minimum, the date and time of the alleged occurrence, the location, the names of all individuals involved, and a description of the behavior that is alleged to have occurred within the ASC and to have constituted mistreatment, neglect or abuse or other serious harm.

The ASC regulation does define the terms "mistreatment," "neglect," or "abuse." However, the following definitions from long term care regulations may be helpful in making common sense judgments about whether an allegation fits into one of these categories:

- Neglect - Failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness (42 CFR 488.301).

- Abuse - The willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish (42 CFR 488.301).

In addition, according to the Merriam Webster dictionary, "mistreatment" means to treat badly. It is also a synonym for abuse.

Finally, if there is applicable State law defining mistreatment, neglect or abuse in a healthcare facility, including ASCs, those definitions will apply.

All grievances alleging mistreatment, neglect or abuse that are submitted to any ASC staff member, whether verbally or in writing, must be reported immediately, i.e., as soon as possible, and at least on the same day, by the staff member to an ASC official who has authority to address grievances. The ASC's grievance policies and procedures must

identify the person(s) in the ASC who have the authority to respond to grievances. The ASC is expected to educate staff on their obligation to immediately report all grievances alleging mistreatment, neglect or abuse, including whom they should report the grievance to.

Grievances alleging mistreatment, neglect, abuse or other behavior that endangers a patient should be investigated as soon as possible, given the seriousness of the allegations and the potential for harm to patients. The ASC must conduct a careful investigation, balancing the need for speedy resolution with the need to ascertain all pertinent facts.

If the ASC confirms that the alleged mistreatment, abuse, neglect or other serious harm took place, then the ASC is obligated to report the event to the appropriate local or State authority, or even both. Depending on the specifics of the case and State or local law, the appropriate authority(ies) might include the local police, a State healthcare professional licensing board, a State agency that licenses the ASC, a State ombudsman, etc. The ASC should contact the appropriate authority promptly after it concludes its investigation of the grievance.

Survey Procedures: §§416.50(d)(1)(2), & (3)

- Do the ASC's grievance policies and procedures separately address the process for investigating grievances alleging mistreatment, abuse, neglect or other serious harm? Do the policies and procedures conform to the regulatory requirement?

- Interview staff to determine how they would handle a grievance alleging mistreatment, abuse, neglect or other serious harm? Do they know who to report the grievance to? Do they know that it should be reported immediately?

- Ask the ASC who is the person authorized to handle such grievances. Interview that person to determine if he/she understands the requirements to fully document the allegation, conduct a prompt investigation, and to report substantiated grievances to the proper authority.

- Ask the person authorized to handle such grievances if the ASC has had any grievances alleging mistreatment, neglect, abuse or other serious harm? If the answer is yes, ask to review the files for one or more such grievances. If such grievances were substantiated, verify whether there is documentation that the findings were reported to the appropriate authority.

Q-0227

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(e) Standard: Exercise of rights and respect for property and person.

(1) The patient has the right to the following:

(i) Be free from any act of discrimination or reprisal.

Interpretive Guidelines: §416.50(e)(1)(i)

The ASC may not take punitive action as a reprisal or discriminate against a patient. This includes reprisals or discrimination against a patient merely because he or she has exercised her rights. The ASC's patients' rights policies and procedures must indicate that the ASC does not engage in reprisals or discriminatory behavior.

Survey Procedures: §416.50(e)(1)(i)

- Interview staff to determine whether they are aware that the ASC may not discriminate against patients, or take punitive actions against any patient as a reprisal for some act on the patient's part.

- Review the ASC's policies and procedures to determine whether it is clear that patients, or their representatives, or surrogates may exercise their rights without fear of reprisal.

- Interview staff about how a patient who has filed a grievance or otherwise exercises his/her rights is treated. Is staff aware that they should not treat patients differently if the patient files a grievance?

Q-0228

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(e) Standard: Exercise of rights and respect for property and person.

[(1) The patient has the right to the following:]

(ii) Voice grievances regarding treatment or care that is (or fails to be) provided.

Interpretive Guidelines: §416.50(e) (1)(ii)

This requirement complements the requirement for the ASC to have a grievance system. Patients have the right to express a grievance regarding the treatment or care they receive in the ASC.

The patient, or the patient's representative or surrogate, as appropriate, may file a grievance, verbally or in writing, before the date of the scheduled procedure, on the date of the procedure, or after the date of the procedure. The regulation does not prescribe any limitation as to when a patient may submit a grievance. However, it is understood that, if a substantial amount of time has passed since the care episode addressed in the grievance, e.g., several years, that it may, depending on the nature of the grievance, be harder for the ASC to investigate the grievance and ascertain the pertinent facts.

Survey Procedures: §416.50(e) (1)(ii)

- Interview ASC staff to determine if they are aware of the patient's right to file a grievance.

- If the survey is related to a complaint alleging that an ASC ignored a patient's grievance, include that medical record in the sample and review it to determine if there is any evidence of a grievance as well as of action to respond to the grievance.

Q-0229

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(e) Standard: Exercise of rights and respect for property and person.

[(1) The patient has the right to the following:]

(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.

Interpretive Guidelines: §416.50(e)(1)(iii)

As in the case of advance directives, the patient has the right to make an informed decision regarding his/her care in the ASC. The right to make informed decisions means that the patient or patient's representative or surrogate is given the information needed in order to make "informed" decisions regarding his/her care. The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis, and prognosis. Furthermore, it includes the patient's participation in the development of their plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the ASC. The patient or the patient's representative or surrogate should receive adequate information, provided in a manner that the patient or the patient's representative or surrogate can understand, to assure that the patient can effectively exercise the right to make informed decisions.

ASCs must utilize an informed consent process that assures patients or their representatives or surrogates are given the information and disclosures needed to make an informed decision about whether to consent to a surgical procedure in the ASC. The primary purpose of the informed consent process in the ASC is to ensure that the patient, or the patient's representative or surrogate, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible physician's professional judgment. Informed consent must be obtained and the informed consent form must be signed by the patient, or as appropriate, the patient's representative, and placed in the

patient's medical record, prior to surgery. It would be acceptable if the ASC required the physician(s) who perform procedures in the ASC to obtain the patient's informed consent outside of the ASC, prior to the date of the surgery, since this might allow more time for discussion between the patient and physician than would be feasible on the date of the surgery. In such cases, the physician must follow the ASC's informed consent process. In all cases, the ASC must ensure that the patient's informed consent is secured prior to the start of the surgical procedure, and that this consent is documented in the patient's medical record. (See the interpretive guidelines for §416.47(b)(7) concerning documentation in the medical record of informed consent.)

Given that ASC surgical procedures generally entail use of some form of anesthesia, and that there are risks as well as benefits associated with the use of anesthesia, ASCs should assure that their informed consent process provides the patient with information on anesthesia risks and benefits as well as the risks and benefits of the surgical procedure. The ASC's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent;

- The circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery (see guidance for §416.50(e)(2) & (3);

- The content of the informed consent form and instructions for completing it;

- The process used to obtain informed consent, including how informed consent is to be documented in the medical record;
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery; and

- If the informed consent process and informed consent form are obtained outside the ASC, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery.

If there are additional requirements under State law for informed consent, the ASC must comply with those requirements.

Example of a Well-Designed Informed Consent Process

A well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used;

- The indications for the proposed surgery;

- Material risks and benefits for the patient related to the surgery and

anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;

- Treatment alternatives, including the attendant material risks and benefits;

- The probable consequences of declining recommended or alternative therapies;

- Who will conduct the surgical intervention and administer the anesthesia;

- Whether physicians other than the operating practitioner will be performing important tasks related to the surgery, in accordance with the ASC's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;

- Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the ASC.

Survey Procedures: §416.50(e)(1)(iii)

- Determine whether the ASC has an informed consent policy that meets the regulatory requirements.

- Verify in the survey sample of medical records that there is documentation that informed consent was given prior to the surgical procedure. Was the consent signed by the patient or as appropriate, the patient's representative?

- As part of the process of following one or more cases from start to finish, determine whether there is an informed consent that was executed prior to the surgery date on file, and if not, observe whether the ASC obtains informed consent.

- Check the records of patients who are in recovery on the date(s) of the survey to verify that there is documentation of informed consent.

- Interview patients to determine whether they recall being asked to consent to the procedure, and whether the risks and benefits were discussed with them at that time.

Q-0230
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(e) Standard: Exercise of rights and respect for property and person.

(2) If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

Interpretive Guidelines: §§416.50(e)(2)& (3)

A patient who has been determined to be incompetent under a State legal process is not capable of exercising his or her rights independently. For such patients, the person appointed under State law to act on the patient's behalf may exercise any and all of the rights afforded to any ASC patient.

In addition, a competent patient may wish to delegate his/her right to make informed decisions to another person. To the degree permitted by State law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated, for example, if a complication requiring a treatment decision arises during a procedure. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative or surrogate so that informed healthcare decisions can be made for the patient.

Survey Procedures: §§416.50(e)(2) &(3)

- Verify that there is a policy addressing the exercise of rights on behalf of a patient judged legally incompetent.

- Verify that there is a policy addressing the delegation by a patient of the exercise of rights to a representative.

Q-0231
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

(1) Personal privacy.

Interpretive Guidelines: §416.50(f)(1)

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, dressing), during medical/surgical treatments, and when requested as appropriate.

People not involved in the care of the patient should not be present without the patient's consent while the patient is being examined or treated. Video or other electronic monitoring or recording methods should not be used when the patient is being examined without the patient's consent. If a patient requires assistance during toileting and other personal hygiene activities, staff should assist, giving the utmost attention to the patient's need for privacy. Privacy should also be afforded when staff visits the patient to discuss clinical care issues or conduct any examination.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when there is an emergency and transfer to a hospital is pending.

In most situations, security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc. are not generally affected by this requirement.

Survey Procedures: §416.50(f)(1)

- Observe whether patients are provided privacy during examinations, activities concerning personal hygiene, and discussions regarding the patient's health status or healthcare, and any other appropriate situations.

Q-0232

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

(2) Receive care in a safe setting.

Interpretive Guidelines: §416.50(f)(2)

Each patient should receive care in an environment that a reasonable person would

consider to be safe. The ASC staff should follow current standards of practice for patient environmental safety, infection control, and security. The ASC staff should also provide protection for the patient's emotional health and safety as well as the patient's physical safety. Respect, dignity, and comfort would be components of an emotionally safe environment.

Survey Procedures: §416.50(f)(2)

- Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the ASC.

- Review safety, infection control and security documentation to determine if the ASC is identifying problems, evaluating those problems, and taking steps to ensure a safe patient environment.

- Observe the environment where care and treatment are provided.

- Review policy and procedures to see what steps the facility takes to curtail unwanted visitors and/or contaminated materials.

- Interview staff and patients to see if either have any concerns about the safety of the setting.

Q-0233

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

(3) Be free from all forms of abuse or harassment.

Interpretive Guidelines: §416.50(f)(3)

An ASC must prohibit all forms of abuse, neglect (as a form of abuse), and harassment from staff, other patients, or visitors. The ASC must have mechanisms/methods in place ensure that patients are free from all forms of abuse, neglect, or harassment.

As discussed in the guidance for §416.50(d), abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish or mental illness and neglect is the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. The Merriam Webster Dictionary defines "harassment" as creating an unpleasant or hostile situation, especially by uninvited and unwelcome verbal or physical conduct.

The following components are suggested as necessary for effective protection from

abuse, neglect or harassment:

Prevent - Persons with a record of abuse or neglect should not be hired or retained as employees. It is recommended that the ASC have a process in place to screen all applicants for employment or privileges to practice in the ASC.

Identify - The ASC should create and maintain a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect.
Train - The ASC, during its orientation program, and through an on-going training program, should provide all employees with information regarding patient abuse and neglect, including who in the ASC is authorized to receive and handle allegations of abuse and neglect.

Investigate - The ASC ensures, in a timely and thorough manner, an objective investigation of all allegations of abuse, neglect, or mistreatment. This includes investigation not only of grievances from patients or their representatives, for which the grievance process prescribed in §416.50(d) must be used, but also allegations from any other source.

Respond - The ASC should assure that any and all incidents of abuse, neglect, or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with the applicable local, State, or Federal law.

Survey Procedures: §416.50(f)(3)

Examine the extent to which the ASC has a system in place to protect patients from abuse, neglect, and harassment of all forms, whether from staff, other patients, visitors, or other persons. In particular, determine the extent to which the ASC addresses the following issues:

- Does the ASC have policies and procedures for investigating allegations of abuse and neglect in addition to the required grievance process that applies to allegations from patients or their representatives?

- Does the ASC use the same process as for grievances alleging abuse and neglect? If not, what is the ASC's policy and process, including the process for training staff?

- Interview staff to determine if staff members know what to do if they witness abuse and neglect.

- Ask the ASC if it has had any allegations of patient abuse or neglect from any source during the past year? If it has, ask the ASC to provide the files and to describe how the matter was handled.

- Review the records to see if the appropriate agencies were notified in accordance with State and Federal laws regarding incidents of substantiated abuse and

neglect?

Q-0234
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(g) Standard: Confidentiality of Clinical Records

The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR Parts 160 and 164.

Interpretive Guidelines: §416.50(g)

Section 45 CFR Parts 160 and 164, generally known as the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security rules, establish standards for health care providers and suppliers that conduct covered electronic transactions, such as ASCs, among others, for the privacy of protected health information (phi), as well as for the security of electronic phi (ephi).

> **45 CFR 160.103** defines "Protected health information" as "individually identifiable health information" with specified exceptions and limitations.
>
> **45 CFR 160.103** defines "Individually identifiable health information" as "information that is a subset of health information, including demographic information collected from an individual, and:
>
> (1) Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and
>
> (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and
>
> (i) That identifies the individual; or
>
> (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual."

Privacy Rule

Individually identifiable health information that is held by HIPAA Covered Entities is protected under the Privacy Rule. Such information held by the "business associates" of Covered Entities is protected through contractual requirements in their contracts with the Covered Entities.

The Privacy Rule requires ASCs that are HIPAA Covered Entities to engage in activities such as:

- Notifying patients about their privacy rights and how their information can be used;

- Adopting and implementing privacy procedures for the ASC;

- Training employees so that they understand the privacy procedures;

- Designating an individual to be responsible for seeing that the privacy procedures are adopted and followed within the ASC; and

- Securing patient records containing individually identifiable health information so that they are not readily available to those who do not need them.

To ease the burden of complying with these requirements, the Privacy Rule gives needed flexibility for ASCs to create their own privacy procedures, tailored to fit their size and needs. This scalability provides a more efficient and appropriate means of safeguarding protected health information than would any single standard. For example:

- The privacy official at a small ASC may be the office manager, who will have other non-privacy related duties; the privacy official at a very large, high volume ASC may be a full-time position.

- The training requirement may be satisfied by a small ASC's providing each new member of the workforce with a copy of its privacy policies and documenting that new members have reviewed the policies; whereas a very large ASC may provide training through live instruction, video presentations, or interactive software programs.
- The policies and procedures of small ASCs may be more limited under the Rule than those of a very large ASC, based on the volume of health information maintained and the number of interactions with those within and outside of the healthcare system.

The Department of Health and Human Services Office of Civil Rights, which is charged with responsibility for enforcing the Privacy Rule, provides more detailed information at the following website: http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html
A summary of the Privacy Rule's requirements may be found at:
http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html

Security Rule

The Department of Health and Human Services (HHS), Office of Civil Rights, also established standards, as required under HIPAA, for the security of health information. The Security Rule specifies a series of administrative, technical, and physical security standards with which covered entities must comply to ensure the confidentiality, integrity, and availability of all ephi that the covered entity creates, receives, maintains, or transmits. The standards include required and addressable implementation specifications. Unlike the Privacy Rule, which applies to protected health information in

both electronic and non-electronic forms, the Security Rule only applies to phi in electronic form. More information on the Security Rule may be found at the following Web site:
http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html

Expectations for Surveyors

Surveyors are not expected to have detailed knowledge of the requirements of the Privacy and Security Rules, but instead are to focus on the steps the ASC takes to protect the confidentiality of clinical records, as well as to assure a patient's access to his/her own clinical record. If broader violations of the Privacy Rule are suspected, the case may be referred to the Regional Office, which may in turn forward the information to the Office of Civil Rights.

The ASC must have sufficient safeguards to ensure that access to all clinical records is limited to those individuals designated by law, regulation, and policy, or duly authorized by the patient to have access. No unauthorized access or dissemination of clinical records is permitted. Clinical records must be kept secure and only viewed when necessary by those persons participating in some aspect in the patient's care.
The right to the confidentiality of clinical records means safeguarding the content of information, including patient paper records, video, audio, and/or computer-stored information from unauthorized disclosure without the specific informed consent of the patient or patient's representative.

Confidentiality applies to both central storage of the closed clinical records and to open clinical records in use throughout the ASC.

Survey Procedures: §416.50(g)

- What policies and procedures does the ASC have in place to prevent the release or disclosure of individually identifiable patient information?

- Observe whether patient information is visible in areas where it can be viewed by visitors or other patients? How likely is it that an unauthorized individual could read and/or remove a patient's medical record?

- What security measures are in place to protect the patient's medical records?

Q-0240
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51 Condition for Coverage – Infection control

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

Interpretive Guidelines: §416.51

This regulation requires the ASC to maintain an active program for the minimization of infections and communicable diseases. The National Institute of Allergy and Infectious Diseases (NIAID) defines an infectious disease as a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product. An infectious agent is defined by the NIAID as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions. NIAID defines a communicable disease as a disease associated with an agent that can be transmitted from one host to another. (See NIAID website glossary)

The ASC's infection control program must:

- Provide a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases;
- Be based on nationally recognized infection control guidelines;
- Be directed by a designated health care professional with training in infection control;
- Be integrated into the ASC's QAPI program;
- Be ongoing;
- Include actions to prevent, identify and manage infections and communicable diseases; and
- Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.

The ambulatory care setting, such as an ASC, presents unique challenges for infection control, because: patients remain in common areas, often for prolonged periods of time; surgical prep, recovery rooms and ORs are turned around quickly; patients with infections/communicable diseases may not be identified; and there is a risk of infection at the surgical site. Furthermore, due to the short period of time patients are in an ASC, the follow-up process to identify infections associated with the ASC requires gathering information after the patient's discharge rather than directly. It is essential that ASCs have a comprehensive and effective infection control program, because the consequences of poor infection control can be very serious. In recent years, for example, poor infection control practices related to injections of medications, saline or other infusates in some ASCs have resulted in the transmission of communicable diseases, such as hepatitis C, from one patient infected with the disease prior to his/her ASC visit to other ASC patients, and a requirement to notify thousands of other ASC patients of their potential exposure.

Survey Procedures: §416.51

One surveyor is responsible for completion of the Infection Control Surveyor Worksheet, Exhibit 351, which is used to facilitate assessment of compliance with this Condition. However, each member of the survey team, as he or she conducts his/her survey assignments, should assess the ASC's compliance with the Infection Control regulatory

requirements.

Q-0241
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(a) Standard: Sanitary Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

Interpretive Guidelines: §416.51(a)

The ASC must provide and maintain a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases. All areas of the ASC must be clean and sanitary. This includes the waiting area(s), the pre-surgical prep area(s), the recovery room(s), and the operating or procedure rooms. The ASC must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and sanitary environment. Policies and procedures for a sanitary and functional environment should address the following:

- Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation;
- Maintaining safe air handling systems in areas of special ventilation, such as operating rooms;
- Techniques for food sanitation if employee food storage and eating areas are provided;
- Techniques for cleaning and disinfecting environmental surfaces, carpeting, and furniture;
- Techniques for disposal of regulated and non-regulated waste; and
- Techniques for pest control.

These activities must be conducted in accordance with professionally recognized standards of infection control practice. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

Survey Procedures: §416.51(a)

Using the specific questions on the infection control survey worksheet related to environmental infection control to guide you:

- Observe throughout the ASC the cleanliness of the waiting area(s), the recovery room(s), the OR/procedure rooms, floors, horizontal surfaces, patient equipment,

air inlets, mechanical rooms, supply, storage areas, etc.

- Interview staff to determine whether cleaning/disinfection takes place at the appropriate frequencies, using suitable EPA-registered agents. Ask for supporting documentation to confirm what staff say in interviews.

- Determine whether the ASC has a procedure for decontamination after gross spills of blood or other bodily fluids.

- Determine whether used sharps are disposed of properly.

- Determine whether the ASC re-uses devices marketed for single use, and if so, does it send them to an FDA-approved vendor for reprocessing?

Q-0242

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(b) Standard: Infection control program.

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. […]

Interpretive Guidelines: §416.51(b)

The ASC must maintain an ongoing program to prevent, control, and investigate infections and communicable diseases. As part of this ongoing program, the ASC must have an active surveillance component that covers both ASC patients and personnel working in the facility. Surveillance includes infection detection through ongoing data collection and analysis.

The ongoing program must be based on nationally recognized infection control guidelines that the ASC has selected, after a deliberative process. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

The ASC should select one or more sets of guidelines that enable it to address the following key functions of an effective infection control program:

- Maintenance of a sanitary ASC environment (see requirements of §416.51(a));

- Development and implementation of infection control activities related to ASC personnel, which, for infection control purposes, includes all ASC medical staff,

employees, and on-site contract workers (e.g., nursing staff employed by associated physician practice who also work in the ASC, housekeeping staff, etc);

- Mitigation of risks associated healthcare-associated infections:
- Identifying infections;
- Monitoring compliance with all policies, procedures, protocols and other infection control program requirements;
- Program evaluation and revision of the program, when indicated;

The following provides a more detailed overview of the types of activities related to these key functions.

ASC staff-related activities:

- Evaluating ASC staff immunization status for designated infectious diseases, for example, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP);
- Policies articulating the authority and circumstances under which the ASC screens its staff for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as required under local, state, or federal public health authority;
- Policies articulating when infected ASC staff are restricted from providing direct patient care or required to remain away from the facility entirely;
- New employee and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases; and
- Methods to evaluate staff exposed to patients with infections and communicable diseases.

Mitigation of risks contributing to healthcare-associated infections (HAI):

For the purposes of its surveillance activities in an acute care setting, the CDC defines an HAI as a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the ASC.

HAIs may be caused by infectious agents from endogenous or exogenous sources. Endogenous sources are body sites, such as the skin, nose, mouth, gastrointestinal (GI) tract, or vagina that are normally inhabited by microorganisms. Exogenous sources are those external to the patient, such as patient care personnel, visitors, patient care

equipment, medical devices, or the health care environment.

HAI risk mitigation measures include:

Surgery-related infection risk mitigation measures:

- Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as protocol to assure that antibiotic prophylaxis to prevent SSI for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery; and

- Addressing aseptic technique practices used in surgery, including sterilization or high-level disinfection of instruments, as appropriate.

- Other ASC healthcare-associated infection risk mitigation measures:

- Promotion of hand hygiene among staff and employees, including utilization of alcohol-based hand sanitizers;

- Measures specific to the prevention of infections caused by organisms that are antibiotic-resistant;

- Measures specific to safe practices for injecting medications and saline or other infusates;

- Requiring disinfectants and germicides to be used in accordance with the manufacturers' instructions;

- Appropriate use of facility and medical equipment, including air filtration equipment, UV lights, and other equipment used to control the spread of infectious agents;

- Educating patients, visitors, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the ASC and in the community.

Identifying Infections

The ASC must conduct monitoring activities throughout the entire facility in order to identify infection risks or communicable disease problems. The ASC should document its monitoring/tracking activities, including the measures selected for monitoring, and collection and analysis methods. Activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC's National Healthcare Safety Net (NHSN). Monitoring includes follow-up of patients after discharge, in order to gather evidence of whether they have developed an infection associated with their stay in the ASC. See discussion of §416.44(a)(3).

The ASC must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

Monitoring Compliance

It is not sufficient for the ASC to have detailed policies and procedures governing infection control; it must also take steps to determine whether the staff of the ASC adhere to these policies and procedures in practice. Are staff washing their hands prior to providing care to patients? Do personnel who prepare injections comply with all pertinent protocols? Is equipment properly sterilized or disinfected? Is the facility clean? The ASC must demonstrate that it has a process in place for regularly assessing infection control compliance.

Program Evaluation

See the guidance for §416.51(b)(2), which requires that the infection control program must be an integral part of the ASC's quality assessment and performance improvement program.

An ASC presents different challenges for infection control as patients at varying levels of wellness are gathered in waiting or recovery areas, including the elderly, immuno-compromised patients, pre- and post-operative patients, and individuals with active or incubating infectious and communicable diseases. The length of stay for such individuals can range from brief to all day. Additionally, as ASCs are performing more invasive procedures, the level of risk for developing and transmitting infections and communicable diseases for patients and heath care workers increases. The ASC should design its infection control program with these challenges in mind. For instance, the ASC should take appropriate control measures for those individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. When such individuals are identified, the ASC could, for example, implement such prevention measures that would include prompt physical separation, implementation of respiratory hygiene/cough etiquette protocols, and appropriate isolation precautions based on the routes of transmission of the suspected infection.

Survey Procedures: §416.51(b)

- Use the infection control tool to assist in assessing compliance with this standard.

- Determine that there is an ongoing program for the prevention, control, and investigation of infections and communicable diseases among patients and ASC personnel, including contract workers and volunteers.

- Determine whether the policies and procedures of the program of the infection control program are implemented correctly. Specifically, surveyors should determine whether the ASC:

- Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good hand hygiene);

- Performs monitoring/tracking activities to identify infections; and

- Monitors compliance with all infection control program requirements.

- Review the parameters of the program to determine whether it is consistent with nationally recognized infection control guidelines. Is there documentation that the ASC has developed the procedures and policies of the program based on nationally recognized infection control guidelines?

Q-0243

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(b) Standard: Infection control program.

[…] The program is –

(1) Under the direction of a designated and qualified professional who has training in infection control;

Interpretive Guidelines: §416.51(b) (1)

The ASC must designate in writing, a qualified licensed health care professional who will lead the facility's infection control program. The ASC must determine that the individual has had training in the principles and methods of infection control. Note that certification in infection control, such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CIBC), while highly desirable, is not required, so long as there is documentation that the individual has training that qualifies the individual to lead an infection control program. The individual selected to lead the ASC's infection control program must maintain his/her qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA.

Although CMS does not specify the number of hours that the qualified individual must devote to the infection control program, resources must be adequate to accomplish the tasks required for the infection control program. The ASC should consider the type of surgical services offered at the facility as well as the patient population in determining the size and scope of the resources it commits to infection control. The CDC's HICPAC as well as professional infection control organizations, such as the APIC and the SHEA, publish studies and recommendations on resource allocation that ASCs may find useful.

Survey Procedures: §416.51(b) (1)

- Determine whether a qualified individual has been designated with the responsibility for leading the infection control program.

- Review the personnel file of the infection control individual to determine whether he/she is qualified through ongoing education, training, or certification to oversee the infection control program.

Q-0244

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(b) Standard: Infection Control Program.

[...The program is –]

(2) An integral part of the ASC's quality assessment and performance improvement program; and

Interpretive Guidelines: §416.51(b)(2)

To reflect the importance of infection control the regulations specifically require that the ASC's infection control program must be integrated into its QAPI program. Among other things this means that infection control data and program activities are an ongoing component of the QAPI program, and that actions are taken in response to data analyses to improve the ASC's infection control performance. See the discussion related to §416.43, which articulates the ASC QAPI requirements.

Survey Procedures: §416.51(b)(2)

- Determine whether the ASC's quality assessment and performance program includes measures/indicators and activities related to infection control on an ongoing basis.

- Determine whether there is evidence that the QAPI infection control activities result in specific actions designed to improve infection control within the ASC.

Q-0245

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.51(b) Standard: Infection control program.

The program is –]

(3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

Interpretive Guidelines: §416.51(b)(3)

The ASC's infection control professional must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases within the ASC. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the ASC's infection control outcomes. The plan should be specific to each particular area of the ASC, including, but not limited to, the waiting room(s), the recovery room(s), and the surgical areas. The designated infection control professional must assure that the program's plan of action addresses the activities discussed in the interpretive guidelines for §416.51(b), i.e.,

- Maintenance of a sanitary environment; (See discussion of §416.51(a))
- Development and implementation of infection control measures related to ASC personnel;
- Mitigation of risks associated with patient infections present upon admission;
- Mitigation of risks contributing to healthcare-associated infections;
- Active surveillance;
- Monitoring compliance with all policies, procedures, protocols, and other infection control program requirements;
- Plan evaluation and revision of the plan, when indicated;
- Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable and infectious disease threats and outbreaks; and
- Compliance with reportable disease requirements of the local health authority. (See discussion of §416.44(a)(3))

ASCs are required to have a process to follow up on each patient after discharge, in order to identify and track infections associated with the patient's stay in the ASC. An ASCs is not expected to establish routine post-surgical laboratory testing for infectious diseases, but if it learns of an infection in the post-discharge period from the patient or patient's physician, the ASC might consider inquiring whether there is a lab confirmation of an infectious disease, and, if there are indications that the infection was associated with the patient's stay in the ASC. If the ASC learns of a disease that is reportable under State law (including regulations), they must report it to the appropriate State authorities.

ASCs may delegate portions of this follow-up responsibility to the physicians on the ASC's staff who will see the patients in their office post-discharge only if the ASC's process includes a mechanism for ensuring that the results of the follow-up are reported back to the ASC and documented in the patient's medical record.

Survey Procedures: §416.51(b)(3)

- Ask the infection control professional to describe actual examples of how, as a result of the action plan, infection control issues were identified and corrective or preventive actions were taken.

- Ask for documentation of how those actions were evaluated to assure that they resulted in improvement.

- Ask the infection control professional to review the ASC's infection control plan of action with you, explaining how it addresses the fundamental elements of an infection control program.

- Does the plan address all the basic elements of infection control?

- Ask the ASC's leadership how it tracks infections among patients and staff.

- Ask for documentation of this tracking – is there tracking of all patients?

- Ask the ASC's leadership what diseases are reportable to the State to verify the ASC's awareness of applicable reporting requirements.

- Ask the ASC if it has ever reported a reportable disease to the State. If yes, review the ASC's documentation of the case.

Q-0260

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52 Condition for coverage – Patient Admission, Assessment and Discharge

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.
Interpretive Guidelines §416.52

The core objectives of this condition are to ensure that:

- The patient can tolerate a surgical experience;

- The patient's anesthesia risk and recovery are properly evaluated

- The patient's post-operative recovery is adequately evaluated;

- The patient received effective discharge planning; and

- The patient is successfully discharged from the ASC

(See 72 FR 50477, August 31, 2007.)

All elements of the specific requirements of this condition concerning pre- and post-surgical assessments, together with the patient assessment requirements in the surgical services CfC at§416.42(a) , must be met. Deficiencies related to §416.42(a), concerning the need for a physician to evaluate the patient for anesthesia risk and surgical procedure risk prior immediately before surgery, and for anesthesia recovery prior to discharge are to be considered when determining whether the requirements of this Condition have been met.

Q-0261

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.52(a): Standard: ***Patient Assessment and Admission.***

(1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must--

(i) Include the timeframe for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

Interpretive Guidelines §416.52(a)(1)

Guidance pending and will be updated in future release.

Q-0262

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.52(a) Standard: Admission and Pre-surgical Assessment

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical **assessment** ***must include*** **documentation of any allergies to drugs and biologicals.**
Interpretive Guidelines: §416.52(a)(2)-*(3)*

Guidance pending and will be updated in future release.

Q-0263

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.52(a) Standard: Admission and Pre-surgical Assessment

(4) **The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.**

Interpretive Guidelines: §416.52(a)(*4*)

Guidance pending and will be updated in future release.

Q-0264

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52(b) Standard: Post-surgical Assessment.

(1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Post-surgical needs must be addressed and included in the discharge notes.

Interpretive Guidelines: §416.52(b)

Each patient must be assessed after the surgery is completed. In accordance with the requirements of §416.42(a)(2), a physician or anesthetist must assess each patient for recovery from anesthesia after the surgery. See the interpretive guidelines for §416.42(a)(2) for a discussion of the requirements for a post-anesthesia assessment.

In addition, each post-surgical patient's overall condition must be assessed and documented in the medical record, in order to determine how the patient's recovery is proceeding, what needs to be done to facilitate the patient's recovery, and whether the patient is ready for discharge or in need of further treatment or monitoring.

Except for the assessment of the patient's recovery from anesthesia, the assessment may be performed by a physician, another qualified practitioner, or a registered nurse with post-operative care experience who is permitted, under applicable State laws as well as general standards of practice and the ASC's clinical policy, to assess patients' post-operatively.

If the assessment identifies post-surgical patient needs that must be addressed in order for the patient to be safely discharged, or, in the case of patients who develop needs that

exceed the capabilities of the ASC, appropriately and timely transferred to a hospital for further care, the ASC must address those patient needs. This must be documented in the discharge notes in the patient's medical record.

Survey Procedures: §416.52(b)

- Verify through observation of post-surgical patient care and through record review whether the ASC evaluates each patient after surgery, both for recovery from anesthesia, as required under §416.42(a)(2), and for his/her overall recovery from the surgery and suitability for discharge.

- Are the post-surgical assessments performed by qualified personnel, i.e., a physician or anesthetist assesses the recovery from anesthesia, while the overall assessment is performed by a physician, other licensed practitioner or RN with appropriate experience in post-operative care? Where an RN performs an assessment, is there documentation of the RN's qualifications to do so?

- Does the ASC identify patient needs related to safe discharge, or, as applicable, does it identify patients who require transfer to a hospital for further treatment that exceeds the ASC's capabilities? Do the records reflect actions by the ASC to address the needs it has identified?

- Do the medical records reflect the post-surgical assessment, needs identified, and actions taken by the ASC to address those needs in the medical record's discharge notes?

Q-0265

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52(c) Standard: Discharge. The ASC must -

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow-up appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for follow-up care.

Interpretive Guidelines: §416.52(c)(1)

Each patient, or the adult who accompanies the patient upon discharge, must be provided with written discharge instructions.

Either before the surgery or before discharge each patient must be provided with:

- Prescriptions they will need to fill associated with their recovery from surgery;

- Written instructions that specify actions the individual should take in the immediate post-operative, post-discharge period to promote their recovery from the surgery; warning signs of complications to be alert for, etc.

- How to contact the physician who will provide follow-up care to the patient. When appropriate, the ASC must make an appointment with the physician for follow-up care.

The ASC must also provide supplies, such as gauze, bandages, etc., sufficient for the patient's needs through the first night after the surgery.

Survey Procedures: §416.52(c)(1)

- Determine whether there is a copy of the discharge instructions provided to the patient in the patient's medical record.

- Look at the discharge instructions in the sample of records under review, as well as for patients being discharged while the ASC is being surveyed. Do the discharge instructions include post-operative care instructions for the patient? Do they indicate if the patient was provided prescriptions, if applicable? Do they provide physician contact information?

- Ask the ASC when and how it schedules follow-up appointments with the physician for patients.

- Ask the ASC what types of supplies it typically provides to patients upon discharge. Observe whether patients being discharged during the survey are provided any supplies to cover their overnight needs.

Q-0266

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.52(c) Standard: Discharge.

The ASC must -

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

Interpretive Guidelines: §416.52(c)(2)

No patient may be discharged from the ASC unless the physician who performed the surgery or procedure signs a discharge order. The ASC must ensure that physicians follow applicable State laws as well as generally accepted standards of practice and ASC policy when determining that a patient has recovered sufficiently from surgery and may be discharged from the ASC, or, as applicable, that the patient must be transferred to

another healthcare facility that can provide the ongoing treatment that the patient requires and that the ASC is unable to provide. It is permissible for the operating physician to write a discharge order indicating "the patient may be discharged when stable." (73 FR 68721). In such cases there must be documentation of when patient was stable. It is expected that a patient will actually leave the ASC within 15 – 30 minutes of the time when the physician signs the discharge order or when he or she was found to be stable, whichever happens later.

Survey Procedures: §416.52(c)(2)

- Determine whether there is a discharge order, signed by the physician who performed the surgery/procedure, in the sample of medical records being reviewed.

- Determine whether there is a discharge order signed by the physician for patients being discharged while the survey takes place.

Q-0267

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52(c) Standard: Discharge.

The ASC must -

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

Interpretive Guidelines: §416.52(c)(3)

Unless the physician who is responsible for the patient's care in the ASC has exempted the patient, the ASC may not discharge any patient who is not accompanied by a responsible adult who will go with the patient after discharge. ASCs would be well-advised to develop policies that address what criteria a physician should consider when deciding a patient does not need to be discharged in the company of a responsible adult. Exemptions must be specific to individual patients, not blanket exemptions to a whole class of patients.

Survey Procedures: §416.52(c)(3)

- Do the medical records being review identify for each patient the responsible adult who will accompany the patient after discharge or, alternatively, a specific exemption or this patient from this requirement by the physician?

- Observe whether the ASC ensures an adult accompanies patients discharged while the survey is taking place, unless the patient has been specifically exempted from this requirement.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R200SOMA	02/21/2020	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X-Organ Transplant Program and Appendix Z - Emergency Preparedness	02/21/2020	N/A
R137SOM	04/01/2015	Revisions to State Operations Manual (SOM) Appendices A, G, L and T related to Hospitals, Rural Health Clinics, Ambulatory Surgical Centers and Swing Beds	03/27/2015	N/A
R99SOM	01/31/2014	Revised State Operations Manual (SOM) Appendices A, I, L, and W	01/31/2014	N/A
R95SOM	12/12/2013	Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers and Appendix W, Interpretive Guidelines for Critical Access Hospitals	06/07/2013	N/A
R89SOM	08/30/2013	Revised State Operations Manual (SOM) Appendices A, I, L, and W – Rescinded and replaced by Transmittal 99	08/30/2013	N/A
R84SOM	06/07/2013	Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers and Appendix W, Interpretive Guidelines for Critical Access Hospitals – Rescinded and replaced by Transmittal 95	06/07/2013	N/A
R76SOM	12/22/2011	Clarifications to Appendix L, Ambulatory Surgical Center Interpretive Guidelines – Obtaining Consent Before Observing Surgical Procedures	12/22/2011	N/A

R71SOM	05/13/2011	Clarifications to Appendix L, Ambulatory Surgical Center Interpretive Guidelines – Comprehensive Medical History and Physical (H&P) Assessment and Anesthetic Risk and Evaluation	05/13/2011	N/A
R56SOM	12/30/2009	Revised Appendix L, “Interpretive Guidelines for Ambulatory Surgical Centers”	12/30/2009	N/A
R01SOM	05/24/2004	Initial Release of Pub 100-07	N/A	N/A

From: Kugler, Andrew T.
To: Olney, Jessica@DCA
Subject: Comments to Proposed Rulemaking on SB 501 Anesthesia and Sedation
Date: Wednesday, February 16, 2022 2:42:49 PM
Attachments: CANAComments.pdf

[EXTERNAL]: [redacted]

CAUTION:This message originated from the public internet. Do not open attachments unless you recognize the sender.

Ms. Olney,

Please find attached comments to the proposed rulemaking on SB 501 anesthesia and sedation, filed on behalf of the California Association of Nurse Anesthetists (CANA). Please confirm receipt of these comments.

Thanks very much, Andrew Kugler

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February 16, 2022

VIA E-MAIL

Jessica Olney, Staff Services Manager
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

Re: Comments to Proposed Rulemaking on SB 501 Anesthesia and Sedation

Dear Ms. Olney:

This firm represents the California Association of Nurse Anesthetists ("CANA"). On behalf of CANA, we submit the following comments to the proposed rules on SB 501 Anesthesia and Sedation.

CANA represents the state's certified registered nurse anesthetists ("CRNAs"). CRNAs are highly educated, advanced practice registered nurses who administer anesthesia to all types of patients in all types of healthcare settings, from individual offices to acute care hospitals. Our comments today concern anesthesia administered to dental patients in ambulatory surgery centers ("ASCs").

For decades, upon the order of a licensed dentist, CRNAs have administered general anesthesia at ASCs irrespective of whether the ordering dentist held an anesthesia permit issued by the Dental Board of California (the "Dental Board"). To our knowledge, this arrangement has never been questioned by any accreditation agency, the California Department of Health or the Medical Board of California. And, until recently, we do not believe it was ever questioned by the Dental Board either.

California law requires a dentist to hold an anesthesia permit before ordering the administration of general anesthesia on an "outpatient basis." *See* Business & Professions Code § 1646.1. But the regulations at 16 CCR 1043(b) limit the definition of "outpatient" as follows:

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

For more than thirty years, it was commonly understood that the above definition of "outpatient" did not extend to patients treated at ASCs, meaning that dentists could order the administration

of general anesthesia by a qualified provider (be it a CRNA or anesthesiologist) in an ASC even if they did not hold an anesthesia permit, just as they do in acute care hospitals.

However, we understand the Dental Board has recently taken the contrary position that a dentist must hold a permit when ordering anesthesia in an ASC, presumably because the Dental Board is now interpreting the definition of "outpatient" to only exclude anesthesia that a dentist orders in a general acute care hospital.

The Dental Board's interpretation is misplaced and causing significant confusion. The statutes, rules and regulatory history make clear that an "outpatient" facility in the context of dental anesthesia does not extend to an ASC. Indeed, while Business & Professions Code ("B&P Code") Section 1646.1 requires a dentist to hold a permit before ordering general anesthesia for dental patients on an "outpatient basis," the section also requires that the dentist be physically present in the "**dental office**" when anesthesia is administered. Clearly, by using these terms interchangeably in the same provision, the Legislature intended for the permitting requirement to be limited to aneshtesia administered in dental offices. Otherwise, Section 1646.1 would make no sense, as it would require a permitted dentist to be present for the administration of anesthesia in a dental office but not in an ASC.

Other statutes and regulations lead to the same conclusion, including B&P Code Section 1646.9(a) and 16 CCR 1043.1, which allow a physician to administer anesthesia in a **dentist's office** irrespective of whether the dentist holds an anesthesia permit. Again, these provisions make no sense if permits are required in the ASC setting, as a dentist would **not** have to obtain a permit for a physician to administer anesthesia in his or her office, but would have to obtain a permit for that same physician to administer anesthesia in an ASC where the medical resources are far more extensive.

B&P Code Section 2827, which is part of the Nurse Anesthetist Act, likewise provides:

> The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care facility administration and the appropriate committee, and at the discretion of the physician, dentist or podiatrist. If a general anesthetic agent is administered in a **dental office**, the dentist shall hold a permit…

(Emphasis added.) Significantly, the last sentence of B&P Code Section 2827 was added by AB501, enacted in 2018. In other words, less than four years ago, the Legislature again drew a clear distinction between anesthesia administered in a dental office – which requires a dental anesthesia permit – versus an acute care facility – which does not.

The Legislature's repeated emphasis on the dental office setting is consistent with its original intent in enacting B&P Code Section 1646.1. Indeed, that provision was enacted in 1979 in direct response to certain tragic and high profile anesthesia incidents that had occurred in

dental office settings. The legislative history never mentioned ASCs, as such facilities were just in their infancy at the time, with no more than 100 of them operating in the entire country and no record of dental aneshtesia or other related safety concerns. The Legislature has thus never evidenced an intent to extend the permitting requirement to ASCs. Since 1979, the statutory language has always been focused on anesthesia administered in dental offices.

Despite this focus, the Dental Board adopted a regulatory definition for "outpatient" in 1991 that addressed facilities other than dental offices. Specifically, 16 CCR 1043(b), as originally adopted, read as follows:

> For purposes of this article, outpatient means a patient treated in a treatment facility which is not accredited by the Joint Commission on Health Care Organizations.

Even in 1991, ASCs were still a nascent industry, particularly with respect to dental services, and those that did exist were commonly accredited by the Joint Commission on Accreditation of Health Care Organizations. In that sense, 16 CCR 1043(b), as adopted in 1991, served mostly to confirm that such ASCs, along with the many hospitals that were also then accredited by the Joint Commission, were not subject to the permit requirement of B&P Code Section 1646.1. In doing so, the regulation was arguably consistent with Section 1646.1's focus on dental offices.[1]

The Dental Board amended the "outpatient" definition in 2005. Initially, the Dental Board proposed an amendment that tracked language that had been recommended by a blue ribbon panel of experts:

> For purposes of this article, "outpatient" means a patient treated in a treatment facility which is not accredited by the Joint Commission on Health Care Organizations or by an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248).

(Exhibit A, attached hereto). The Dental Board's initial statement of reasons made clear, though, that the added language was intended to "recognize **additional** accreditation agencies," not to impact how the definition applied to accredited facilities. (Exhibit B, emphasis added).

The Dental Board later amended the proposal in March 2005, adding a specific exclusion (at CANA's request) for "acute care hospitals" to read:

[1] To the extent that the Dental Board intended for the regulatory definition of "outpatient" to extend the dental permit requirement to non-office settings, it arguably conflicted with the underlying statute. CANA's focus here, though, is on obtaining a rule going forward that clarifies the exemption for ASCs.

> For purposes of this article, "outpatient" means a patient treated in a ~~treatment~~ facility which is not licensed by the State of California as an acute care hospital nor accredited by the Joint Commission on Health Care Organizations or an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248).

(Exhibit C).

> Finally, in May 2005, the Dental Board settled on the language that exists today:
>
> For purposes of this article, "outpatient" means a patient treated in a facility which is not accredited by the Joint Commission on Health Care Organizations or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code ~~an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248)~~.

(Exhibit D). It is not clear why the Dental Board dropped the reference to the additional accrediting entities approved by the Medical Board. But it is clear that the final language was again not intended to alter how the definition applied to accredited facilities. In its final statement of reasons, the Dental Board explained that the final modifications were made "to **include** a 'general acute care' hospital **within** the facilities that are not considered outpatient treatment facilities, and correctly references the licensing body and the underlying authority for that definition." (Exhibit E, emphasis added).

In other words, the Dental Board was not trying to eliminate the exemption that ASCs and other accredited facilities already enjoyed; rather, it was seeking to add a new exclusion to the definition of "outpatient" for general acute care hospitals licensed by the Department of Health Services (and defined in Health & Safety Code Section 1250).

Public policy also then supported, and continues to support, a rule that recognizes the value and relative safety of ASCs. A study published in *Health Affairs* in 2014 reported that surgery centers not only get patients back to their homes faster, they are significantly less expensive as compared to hospital outpatient departments.[2] ASCs also play a huge role in increasing access to healthcare, particularly for medically underserved communities who do not have ready access to acute care hospitals. And from a safety standpoint, ASCs are already subject to rigorous accreditation standards that ensure they possess the equipment, personnel, and protocols needed to ensure the safe provision of health care. As noted in a 2014 study, these additional resources make dental anesthesia in ASCs far less likely to result in negative outcomes

[2] *See* http://content.healthaffairs.org/content/33/5/764.abstract?sid=994959e1-ee2b-4d07-8212-7bacd3c89da3.

as compared to dental offices.[3] In short, a dental anesthesia permitting requirement is simply not necessary in an ASC setting, just as it is not necessary in an acute care hospital.

Again, CANA believes that B&P Code Section 1646.1 never applied to ASCs. Nevertheless, given the confusion that has arisen on this issue, we believe that the Dental Board should take this opportunity to clarify the definition in 16 CCR 1043(b) and effectuate the intent of the Legislature. The Dental Board should also update the definition to recognize all of the regulatory bodies that oversee ASCs. The Joint Commission[4] is just one of the agencies approved by the Medical Board of California to accredit outpatient settings. Others include the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) and the American Osteopathic Association/Healthcare Facilities Accreditation Program (HFAP). There is simply no plausible reason for the Dental Board to treat these accreditation agencies differently in the definition of "outpatient." There is also no plausible reason for the Dental Board to treat ASCs regulated by other bodies differently, including ASCs licensed by the California Department of Public Health as "surgical clinics" or certified by Medicare as "ambulatory surgical centers." The definition of "outpatient" should be consistent and fair and effectuate the intent of the Legislature to limit the dental permit requirement to dental offices.

We suggest the following revisions:

§ 1043. Definitions…

(b) For purposes of this article, "outpatient" means a patient treated in a treatment facility which is not (1) licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code; (2) licensed by the California Department of Public Health as a "surgical clinic" pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health & Safety Code; (3) accredited by an accrediting agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 128); or (4) certified to participate in the Medicare Program as an ambulatory surgical center pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.). ~~the Joint Commission on Health Care Organizations or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code~~.

[3] *See Trends in Death Associated with Pediatric Dental Sedation and General Anesthesia* (2014) at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3712625/.

[4] The Joint Commission on Accreditation of Healthcare Organizations is now known simply as "The Joint Commission."

§ 1043.9. Definitions…

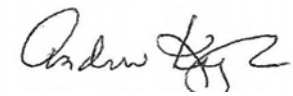
(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility which is (1) licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code; (2) licensed by the California Department of Public Health as a "surgical clinic" pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health & Safety Code; (3) accredited by an accrediting agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 128); or (4) certified to participate in the Medicare Program as an ambulatory surgical center pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.). ~~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~~.

§ 1044. Definitions…

(a) "Outpatient basis" means outpatient setting" as used in Health and Safety Code Sections 1248 and 1248.1 and means all settings where oral conscious sedation is being provided to dental patients with the exception of a treatment facility which is (1) licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code; (2) licensed by the California Department of Public Health as a "surgical clinic" pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health & Safety Code; (3) accredited by an accrediting agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 128); or (4) certified to participate in the Medicare Program as an ambulatory surgical center pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.). ~~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~~.

We appreciate your consideration of these comments. If you have any questions, please do not hesitate to contact me.

Very truly yours,



Andrew Kugler

EXHIBIT A

TITLE 16 DENTAL BOARD OF CALIFORNIA

NOTICE IS HEREBY GIVEN that the Dental Board of California is proposing to take the action described in the Informative Digest. Any person interested may present statements of arguments orally or in writing relevant to the action proposed at a hearing to be held at the Embassy Suites Hotel, 4550 La Jolla Village Drive, San Diego, California 92122. The telephone number is (858) 453-0400. The hearing will be held at 1:30 p.m., or as soon as practicable thereafter, on Friday, January 28, 2005. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Dental Board of California at its office not later than 5:00 p.m. on Monday, January 24, 2005, or must be received by the Dental Board of California at the hearing. The Dental Board of California, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 1614 and 1646.2 of the Business and Professions Code, and to implement, interpret or make specific Sections 1646.1, 1646.2, 1646.3, 1647.3, 1647.4, 1647.4, 1647.6, 1647.7, and 1682 of said Code; the Dental Board of California is considering changes to Division 10, Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Amend 16 California Code of Regulations Section 1043

Existing law authorizes the Board to regulate the General Anesthesia (GA) and Conscious Sedation (CS) Programs. These proposed regulations would make more specific requirements for the program, modernize the language and add additional equipment to the permittee's office.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Cost or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondisretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17651 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Dental Board of California has determined that this regulatory proposal would not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Dental Board of California is not aware of any cost impact that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effects on Housing Costs: None

EFFECT ON SMALL BUSINESS

This proposed action may affect small business.

This proposed change would require a dentist, who holds the GA/CS permit, to have additional equipment in his/her office for GA/CS. The cost has been determined to be not more than $1500.00 per office. This equipment will be mandatory for those offices that do not currently have this equipment already installed.

CONSIDERATION OF ALTERNATIVES

The Dental Board of California must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Dental Board of California has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information, upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Dental Board of California, 1432 Howe Avenue, Suite 85, Sacramento, California 95825.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection, by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below **[or by accessing the website listed below].**

CONTACT PERSON

Inquiries or comments concerning the proposed administrative action may be addressed to:

Name:	Linda M. Madden
Address:	1432 Howe Avenue, Suite 85 Sacramento, California 95825
Telephone:	(916) 263-2300
Fax Number:	(916) 263-2140
E-Mail Address:	linda_madden@dca.ca.gov

The back-up contact person is:

Name:	Anita Dowty
Address:	1432 Howe Avenue, Suite 85 Sacramento, California 95825
E-Mail Address:	anita_dowty@dca.ca.gov

Inquiries concerning the substance of the proposed regulations may be directed to Linda Madden (916) 263-2300, ext. 2327.
Website Access Materials regarding this proposal can be found at www.dbc.ca.gov

DENTAL BOARD OF CALIFORNIA
Article 5. General Anesthesia and Conscious (Moderate) Sedation

Proposed Language

Amend Section 1043 of Division 10 of Title 16 of the California Code of Regulations to read as follows:

§ 1043. Definitions

(a) For purposes of this article, "direct supervision" of general anesthesia means the permittee is in the immediate presence of a patient while general anesthesia is being administered to that patient and that the permittee or a member of the permittee's staff directly monitors the patient at all times.

(b) For purposes of this article, "outpatient" means a patient treated in a treatment facility which is not accredited by the Joint Commission on Health Care Organizations **or by an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248).**

(c) For purposes of Section 1682(a) of the code:

(1) a patient under general anesthesia shall be considered "sedated" for that period of time beginning with the first administration of general anesthetic agents until **that time when** the patient is again conscious with a full return of protective reflexes**, including the ability to respond purposefully to physical stimulation and/or verbal command, when no additional agents will be administered, the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient**;

(2) a patient under conscious sedation shall be considered "sedated" for that period of time beginning with the first administration of conscious sedation agents until that time when no additional agents will be administered, the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient.

(d) For purposes of section 1682(b) of the code, a patient shall be deemed to be "recovering from" conscious sedation or general anesthesia from the time the patient is no longer "sedated" as that term is defined in subsection (c) above until the dentist has evaluated the patient and has determined the patient is responsive, alert, has stable vital signs and is ambulatory and/or capable of being safely transported.

(e) For purposes of this article, "applicant" refers to applicants without permits, as well as permit holders subject to re-evaluation.

NOTE: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.1, and 1682, Business and Professions Code.

§ 1043.1. Permit Requirements.

(a) A licensed dentist does not need a general anesthesia or conscious sedation permit if the general anesthesia or conscious sedation administered in that dentist's office is directly administered by a licensed dentist **or physician and surgeon** who possesses a general anesthesia or conscious sedation permit, whichever is applicable to the type of anesthesia services being provided.

(b) An applicant for a permit to administer **general anesthesia** or order the administration of general anesthesia **by a nurse anesthetist** must be a licensed dentist in

California who:

(1) Has completed a residency program in general anesthesia of not less than one calendar year, that is approved by the **board** ~~Board of Directors of the American Dental Society of Anesthesiology for eligibility for a fellowship in general anesthesia, or has a fellowship in general anesthesia~~; or

(2) Has completed a graduate program in oral and maxillofacial surgery which has been approved by the Commission on **Dental** Accreditation ~~of the ADA~~.

(c) An applicant for a permit to administer or order the administration of conscious sedation must be a licensed dentist in California who meets the requirements set forth in section 1647.3 ~~or 1647.4~~ of the code.

(d) The processing times for a general anesthesia or conscious sedation permit are set forth in section 1061.

NOTE: Authority cited: Sections 1614 and 1646.2, Business and Professions Code. Reference: Sections 1646.2, 1647.3 and 1647.4, Business and Professions Code.

§ 1043.2. Composition of Onsite Inspection and Evaluation Teams

(a) An evaluation team shall consist of two or more persons chosen and approved by the board.

(b) The evaluators must meet one of the criteria in subdivision (b) of section 1043.1 for general anesthesia or the criteria in section 1647.3 ~~or 1647.4(b)~~ of the code for conscious sedation and must have utilized general anesthesia or conscious sedation, whichever is applicable, in a dental practice setting for a minimum of three years immediately preceding their application to be an evaluator, exclusive of any general anesthesia or conscious sedation training.

(c) At least one of the evaluators must have experience in evaluation of dentists administering general anesthesia or conscious sedation. At least one member of the team must have substantial experience in the administration of the method of delivery of anesthesia or sedation used by the dentist being evaluated.

(d) The board may appoint a licensee member of the board to serve as a consultant at any evaluation.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, Business and Professions Code.

§ 1043.3. Onsite Inspections.

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

(a) Office Facilities and Equipment. The following office facilities and equipment shall be available **and shall be maintained in good operating condition**:

(1) An operating theater large enough to adequately accommodate the patient on a table or in an operating chair and permit an operating team consisting of at least

three individuals to freely move about the patient.

(2) An operating table or chair which permits the patient to be positioned so the operating team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.

(3) A lighting system which 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.

(4) Suction equipment which permits aspiration of the oral and pharyngeal cavities. A backup suction device which can operate at the time of general power failure must also be available.

(5) An oxygen delivery system with adequate full face masks and appropriate connectors that is capable of ~~delivering oxygen to the~~ **allowing the administering of greater than 90% oxygen at a 10 liter/minute flow for at least sixty minutes (650 liter "E" cylinder) to the** patient under positive pressure, together with an adequate backup system which can operate at the time of general power failure.

(6) A recovery area that has available oxygen, adequate lighting, suction, and electrical outlets. The recovery area can be the operating theater.

(7) Ancillary equipment: ~~which must include the following maintained in good operating condition:~~

(A) Laryngoscope complete with adequate selection of blades and spare batteries and bulb. (This equipment is not required for conscious sedation.)

(B) Endotracheal tubes and appropriate connectors. (This equipment is not required for conscious sedation.)

(C) **Emergency airway equipment (**~~O~~oral airways~~.~~**, laryngeal mask airways or combitubes, cricothyrotomy device)**.

(D) Tonsillar or pharyngeal type suction tip adaptable to all office outlets.

(E) Endotracheal tube forcep . (This equipment is not required for conscious sedation.)

(F) Sphygmomanometer and stethoscope.

(G) Electrocardioscope and defibrillator. (This equipment is not required for conscious sedation.)

(H) Adequate equipment for the establishment of an intravenous infusion.

(I) Precordial/pretracheal stethoscope.

(J) Pulse oximeter.

(K) Capnograph and temperature device. A capnograph and temperature measuring device are required for the intubated patient receiving general anesthesia. (This equipment is not required for conscious sedation.)

(b) Records. The following records shall be maintained:

(1) Adequate medical history and physical evaluation records~~.~~ **updated prior to each administration of general anesthesia or conscious sedation. Such records shall include, but are not limited to the recording of the age, sex, weight, physical status (American Society of Anesthesiologists Classification), medication use, general health, any known or suspected medically compromising conditions, rationale for anesthesia or sedation of the patient, visual examination of the**

airway, and auscultation of the heart and lungs as medically required.

(2) General anesthesia and/or conscious sedation records, which shall include **a time-oriented record with preoperative,** multiple **interoperative, and postoperative pulse oximetry (every 5 minutes intraoperatively and every 15 minutes postoperatively for general anesthesia) and** blood pressure and pulse readings~~,~~ **(both every 5 minutes intraoperatively for general anesthesia),** 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.

(3) Written informed consent of the patient or if the patient is a minor, his or her parent or guardian.

(c) Drugs. Emergency drugs of the following types shall be available:

(1) ~~Vasopressor~~ **Epinephrine**
(2) ~~Corticosteroid~~ **Vasopressor (other than epinephrine)**
(3) Bronchodilator
(4) Muscle relaxant (This is not required for conscious sedation.)
(5) Intravenous medication for treatment of cardiopulmonary arrest (This is not required for conscious sedation.)
(6) Appropriate drug antagonist
(7) Antihistaminic
(8) Anticholinergic
(9) Antiarrhythmic (This is not required for conscious sedation.)
(10) Coronary artery vasodilator
(11) Antihypertensive (This is not required for conscious sedation.)
(12) Anticonvulsant
(13) Oxygen
(14) 50% dextrose or other antihypoglycemic

(d) Prior to an onsite inspection and evaluation, the dentist shall provide a complete list of his/her emergency medications.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.2, 1646.3, 1647.3, and 1647.6, Business and Professions Code.

§ 1043.4. Evaluation Standards.

The evaluation of an applicant for a permit shall consist of two parts:

(a) Demonstration of a General Anesthesia. A dental procedure utilizing general anesthesia **administered by applicant** must be observed and evaluated. Any anesthesia technique that is routinely employed can be demonstrated. The patient shall be monitored while ~~sedated~~ **anesthetized** and during recovery from ~~sedation~~ **anesthesia** in the manner prescribed by section 1682 of the code.

The applicant for a permit must demonstrate that he or she has knowledge of the uses of the equipment required by section 1043.3(a) and is capable of using that equipment.

(b) Demonstration of a Conscious Sedation. A dental procedure utilizing conscious sedation **administered by the applicant** must be observed and evaluated. Any conscious sedation technique that is routinely employed can be demonstrated. The patient shall be monitored while sedated and during recovery from sedation in the manner prescribed by

section 1682 of the code. The applicant for a permit must demonstrate that he or she has knowledge of the uses of the equipment required by section 1043.3(a) and is capable of using that equipment.

(c) Simulated Emergencies. Knowledge of and a method of treatment must be physically demonstrated by the dentist and his or her operating team for the following emergencies:

(1) Airway obstruction
(2) Bronchospasm
(3) Emesis and aspiration of foreign material under anesthesia
(4) Angina pectoris
(5) Myocardial infarction
(6) Hypotension
(7) Hypertension
(8) Cardiac arrest
(9) Allergic reaction
(10) Convulsions
(11) Hypoglycemia
(12) Syncope
(13) Respiratory depression

NOTE: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, Business and Professions Code.

§ 1043.5. Cancellation of an Onsite Inspection and Evaluation

(a) Whenever a conscious sedation or general anesthesia permittee or applicant cancels an onsite inspection and evaluation, that permittee or applicant shall provide the board with a written reason for the cancellation. If the first cancellation occurs 14 calendar days or more before the date of the scheduled inspection and evaluation, the fee paid shall be applied toward the next scheduled inspection and evaluation. If the cancellation occurs less than 14 calendar days before the scheduled inspection and evaluation, the fee shall be forfeited and a new fee shall be paid before the inspection and evaluation will be rescheduled.

(b) If a permittee or applicant cancels the inspection and evaluation for a second time, all fees are forfeited and the permit shall be automatically suspended or denied unless a new fee has been paid and an onsite inspection and evaluation has been completed within 30 calendar days from the date of the second cancellation.

(c) If a permittee or applicant cancels the scheduled onsite inspection and evaluation for a third time, all fees are forfeited and that cancellation shall be deemed a refusal to submit to an inspection and evaluation, and in accordance with Sections 1646.4 and 1647.7 of the code, the permit shall be automatically revoked or denied as of the date of the third cancellation.

NOTE: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, Business and Professions Code.

§ 1043.6. Grading of Inspection and Evaluation.

(a) The inspection and evaluation shall be graded on a pass/fail system. The grade shall be determined by the board, based upon a recommendation of the evaluators, who shall make independent evaluations and recommendations.

(b) An inspection and evaluation that results in a pass recommendation by both evaluators shall be determined a pass. An inspection and evaluation that results in a pass/fail split recommendation by the evaluators shall be determined a fail.

~~(b)~~**(c)** An ~~dentist~~ 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, pursuant to sections 1646.4(a) and 1647.7(a) of the code, the permit of any dentist who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the dentist of the failure unless, within that time period, the dentist has retaken and passed an onsite inspection and evaluation.

Upon receipt of the appeal request and an additional evaluation fee, the board will schedule an independent reevaluation of the appellant. If a dentist has failed two evaluations, the board will decide the matter and may grant or deny a permit or request further evaluation of the appellant with a board member or other board appointed representative being present.

(d) A dentist who has failed the inspection and evaluation solely on the basis of a failure to demonstrate knowledge and ability in recognition and treatment of any or all of the simulated emergencies may be re-evaluated on the simulated emergencies only without an inspection of the office or demonstration on a patient provided the re-evaluation is within 30 days.

NOTE: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, Business and Professions Code.

§1043.7. Manner of Giving Note of Evaluation.

Upon receipt of either an application for a general anesthesia permit or a conscious sedation permit or where the board determines in any other case that there shall be an onsite inspection and evaluation, the board shall determine the date and time of such evaluation and shall so inform the dentist.

NOTE: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, Business and Professions Code.

§ 1043.8. Renewal.

A general anesthesia or conscious sedation permit shall be renewed biennially upon certification by the permit holder that he/she has met all applicable continuing education requirements for the particular permit, payment of the required fee and if required, successful

completion of an onsite inspection and evaluation.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.1, 1646.5, 1646.6, 1647.2, 1647.5 and 1647.8, Business and Professions Code.

EXHIBIT B

DENTAL BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

Hearing Date: January 28, 2005

Subject Matter of Proposed Regulations: General Anesthesia and Conscious Sedation

Section Affected: 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.6

Specific Purpose of each adoption, amendment, or repeal:

The proposed amendments to 1043, et seq. clarify and make more specific, the requirements for the General Anesthesia (GA) and Conscious Sedation (CS) programs. Some changes modernize language, other changes are based on national standards, and other changes are to add additional equipment to the permittee's office. One piece of equipment is a capnograph, a device that measures CO2 (carbon dioxide) in the body; another is a temperature device that measures the body temperature during GA/CS. Additional emergency airway equipment is also being required (largyngeal mask, cricothyrotomy device.)

Definitions:

(b) Recognizes additional accreditation entities.

(c)(1) Redefines the term "sedated" to better match national standards.

(e) This definition is added for clarity only to avoid the cumbersome use of both the terms "applicant" and "permit holder."

1043.1

(a) In 1998, Section 1646.9 was added to the Business and Professions Code, allowing physicians and surgeons to obtain a GA Permit. This language adds those physicians and surgeons to the regulations for general anesthesia.

(b) Business and Professions Code 2827 allows a nurse anesthetist to administer general anesthesia in a dentist's office, if the dentist has a GA permit. This language adds those nurse anesthetists to the regulations, to clarify that a permit holder can only order another authorized person to administer GA.

(b)(1) The term "board" distinguishes local authority for the programs.

(2) Eliminating "of the ADA" is a modernization of language.

(c) Deletes an obsolete provision of the Code.

1043.2

(b) Deletes an obsolete provision of the Code.

1043.3

The additional language specifies the location for the onsite inspection and evaluation for an applicant who administers GA in multiple locations.

(a) This clarifies the standards for operating equipment.

(5) This language sets a specific requirement for oxygen delivery.

(7)(C) Specifies airway equipment that is required.

(7)(K) The capnograph and temperature measuring device are new equipment required for general anesthesia.

(b)(1) This expands and clarifies the record requirements for the medical history and physical evaluation for each patient.

(b)(2) Clarifies required anesthesia and conscious sedation records.

(c)(1) Drugs: Removes vasopressor and replaces with Epinephrine – a specific drug.

(c)(2) Drugs: Eliminates Corticosteroid and replaces with a vassopressor other than the specific Epinephrine.

(d) This section has been added to assist in the preparation for an on-site inspection and evaluation. This language pertains to the emergency medicines that need to be maintained by the permittee. Establishes no new requirements.

1043.4

This language clarifies who must administer the GA or CS for the evaluation.

1043.6

(b) This new section clarifies what action will be taken based on the evaluators' recommendations.

(d) This new section will allow the permittee who has failed a specific portion of the evaluation, to be re-evaluated only on that specific section, if the re-evaluation is done within 30 days.

Factual Basis:

At the Board meeting of August 2002, the Anesthesia Committee recommended to the Dental Board members that an independent panel of experts be assembled to review existing regulations for these programs. There have been several studies conducted in this field the last several years and board members believe it is prudent for the protection of the public to stay current on GA and CS issues. The Board concurred on forming a panel of experts who were chosen to review the regulations. Those findings were brought to the board on November 4, 2003. There have been several Board committee meetings since that time (refer to Underlying Data on the Initial Statement of Reasons) where the findings were discussed and decisions made about which recommendations to implement. The changes to this regulation have been derived from these reports and findings. Some changes are non-substantive. There will be a new requirement for a capnograph and temperature device in the dentist's office relative to GA and CS. A capnograph is a device that measures CO2 (carbon dioxide) in the body. The temperature device is to monitor the body temperature during the administration of GA/CS.

Underlying Data

1. Minutes from General Anesthesia Committee, November 4, 2004
2. 1998 Anesthesia Survey of The Southern California Society of Oral and Maxillofacial Surgeons (Lylle JJ,au)
3. American Dental Association Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists
4. American Dental Association Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry.
5. American Academy of Periodontology Guidelines: In-Office Use of Conscious Sedation in Periodonitics
6. American Academy of Pediatric Dentistry Guideline on the Effective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients
7. American Association of Oral and Maxillofacial Surgeons Parameters and Pathways: Clinical Practice Guidelines for Oral and Maxillofacial Surgery. Anesthesia is Outpatient Facilities
8. American Association of Oral and Maxillofacial Surgeons Parameters of Care for Oral and Maxillofacial Surgery: A Guide for Practice, Monitoring, and Evaluation, Patient Assessment
9. American Society of Anesthesiologists Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists
10. Letters and attachment by Dr. Roger Kingston on requiring AED training and equipment
11. Letter and related document by Dr. John Yagiela on multiple dosing of triazolam.
12. American Association of Oral and Maxillofacial Surgeons Enteral Sedation Information Kit

13. Dental Organizations for Conscious Sedation Welcome to "Essentials of Oral Sedation"
14. Materials supporting the use of capnography in dentistry

Business Impact:

This regulation will not have a significant adverse economic impact on businesses.

Specific Technologies or Equipment

This regulation would require the permittee to have additional equipment in his/her office. The capnograph is a device that measures CO2 in the body. The temperature device is to monitor the body temperature during the administration of GA/CS. Additional airway equipment is also being required (laryngeal mask, cricothyrotomy device.)

Consideration of Alternatives

No alternatives have been considered because the Dental Board of California has determined this change will increase public protection for those undergoing GA/CS.

EXHIBIT C

STATE OF CALIFORNIA

DEPARTMENT OF CONSUMER AFFAIRS
DENTAL BOARD OF CALIFORNIA

MEMORANDUM

FULL BOARD

To: Committee Members

From: Richard DeCuir, Assistant Executive Officer

Re: Agenda Item 7 - Discussion and Approval of Modified Language re: Proposed Regulation Section 1043 et seq. General Anesthesia/Conscious Sedation

Date: March 10, 2005

Following is modified language for proposed regulation section 1043(b), discussed at the Regulatory Hearing in January, after comments and testimony.

1043. Definitions.

(b) For purposes of this article, "outpatient" means a patient treated in a ~~treatment~~ facility which is not **licensed by the State of California as an acute care hospital nor** accredited by the Joint Commission on Health Care Organizations **or an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248.**

Proposed language as presented at the January Hearing is attached.

EXHIBIT D

State of California Department of Consumer Affairs

DENTAL BOARD OF CALIFORNIA
1432 HOWE AVENUE, SUITE 85, SACRAMENTO, CA 95825-3241
TELEPHONE: (916) 263-2300
FAX: (916) 263-2140

AVAILABILITY OF MODIFIED TEXT

NOTICE IS HEREBY GIVEN that the Dental Board of California has proposed modifications to the text of section(s) 1043 in Title 16 of the California Code of Regulations that were the subject of a regulatory hearing on January 28, 2005. A copy of the modified text is enclosed. Any person who wishes to comment on the proposed modifications may do so by submitting written comments on or before June 3, 2005 to the following:

Dental Board of California

ATTN: Richard E. DeCuir, Assistant Executive Officer

1432 Howe Avenue, Suite 85

Sacramento, CA 95825

DATED: May 16, 2005

GEORGETTA C. GRIFFITH
Interim Executive officer
Dental Board of California

DENTAL BOARD OF CALIFORNIA
Article 5. General Anesthesia and Conscious (Moderate) Sedation

Modified Text

Changes to the originally proposed language for section 1043 are shown by double underline for new text and double strikeout for deleted text.

Amend Section 1043 of Division 10 of Title 16 of the California Code of Regulations to read as follows:

§ 1043. Definitions

(a) For purposes of this article, "direct supervision" of general anesthesia means the permittee is in the immediate presence of a patient while general anesthesia is being administered to that patient and that the permittee or a member of the permittee's staff directly monitors the patient at all times.

(b) For purposes of this article, "outpatient" means a patient treated in a facility which is not accredited by the Joint Commission on Health Care Organizations or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code. ~~by an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248).~~

(c) For purposes of Section 1682(a) of the code:

(1) a patient under general anesthesia shall be considered "sedated" for that period of time beginning with the first administration of general anesthetic agents until **that time when** the patient is again conscious with a full return of protective reflexes, **including the ability to respond purposefully to physical stimulation and/or verbal command, when no additional agents will be administered, the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient;**

(2) a patient under conscious sedation shall be considered "sedated" for that period of time beginning with the first administration of conscious sedation agents until that time when no additional agents will be administered, the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient.

(d) For purposes of section 1682(b) of the code, a patient shall be deemed to be "recovering from" conscious sedation or general anesthesia from the time the patient is no longer "sedated" as that term is defined in subsection (c) above until the dentist has evaluated the patient and has determined the patient is responsive, alert, has stable vital signs and is ambulatory and/or capable of being safely transported.

(e) For purposes of this article, "applicant" refers to applicants without permits, as well as permit holders subject to re-evaluation.

NOTE: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.1, and 1682, Business and Professions Code.

CERTIFICATION RE AVAILABILITY OF LANGUAGE

I certify that the Dental Board of California has complied with the requirements of 1 Cal. Code Reg 44 and that the attached notice and modified text was mailed on May 16, 2005.

The public comment period began on May 16, 2005, and ended on June 3, 2005.

Dated: November 2, 2005

GEORGETTA COLEMAN-GRIFFITH
Assistant Executive Officer
Dental Board of California

EXHIBIT E

DENTAL BOARD OF CALIFORNIA

FINAL STATEMENT OF REASONS

Hearing Date: January 28, 2005

Sections Affected: 16 CCR 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.6

Updated Information
The Initial Statement of Reasons is included in the file. Existing law requires a dentist who wants to administer general anesthesia or conscious sedation in an outpatient setting, obtain a permit. Educational, equipment and facility standards must be met before a permit is granted. These proposed regulations would make specific requirements for the program, modernize the language, and add additional equipment to the permittee's office. The information therein is updated as follows:

1043(b)
The language in Section 1043 was modified to include a "general acute care" hospital within the facilities that are not considered outpatient treatment facilities, and correctly references the licensing body and the underlying authority for that definition.

1043.1(b)(1)
The term "board" clarifies that residency programs approved by the board will be accepted.

1043.1(b)(2)
The Commission on Dental Accreditation, operating under the auspices of the ADA, is the entity that accredits dental education.

1043.3(a)
This new language specifies that the equipment must be maintained in good operating condition.

1043.3(a)(7)
Eliminates duplication of language added to Section 1043.3(a).

1043.4
Clean-up language updates "sedated" to "anesthetized" and "sedation" to "anesthesia".

1043.6(b)
This newly proposed section was removed by the board at its March 10, 2005 meeting after determining that this language would result in an automatic fail if there was a pass/ fail split between the two evaluators.

1043.6(c) now(b)
This language changes the term "dentist" to "applicant" to conform with1043(e).

1043.6(d) now(c)
This new section will allow re-evaluation of an applicant who has failed the simulated emergency portion of the evaluation, if the re-evaluation is done within 30 days.

Material Relied Upon
This item has been updated to include meeting minutes approving modifications to the language and explain the inclusion of the term "Moderate" within the Article 5 title. Also, Item #13 "Dental Organizations for Conscious Sedation Welcome to Essentials of Oral Sedation" has been removed from the list of underlying data because it was not used by the Blue Ribbon Panel on Anesthesia.

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

Small Business Impact
This action will not have a significant adverse economic impact on small businesses.

Consideration of Alternatives
No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Objections or Recommendations/Responses
The following recommendations were received:

An electronic transmission was received on March 21, 2005 from Patrick Shannon on behalf of the California Association of Nurse Anesthetists (CANA), suggesting three amendments to the regulation. Joe Berkheart, immediate past president of CANA presented these recommendations at the regulatory hearing on January 28, 2005.

Section 1043.1(b)
At the hearing, DCA Legal Counsel Norine Marks pointed out that the suggested language for 1043.1(b) "An applicant for a permit to administer general anesthesia or order the administration of general anesthesia by a nurse anesthetist or by a physician and surgeon who does not possess a general anesthesia permit must be a licensed dentist in California who:" is inconsistent with the statute, 1646.9.

Section 1043.1
CANA also recommended adding a new subsection to 1043.1:
(e) A licensed dentist does not need a general anesthesia or conscious sedation permit if the general anesthesia or conscious sedation is administered in a facility accredited by the Joint Commission on Health Care Organizations, licensed as a hospital or by an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248). Legal Counsel Marks said that this would be confusing according to statutes 1646.1 and 1647.2, which clearly state when a permit is needed, as opposed to CANA's recommendation to specify when a permit is not needed.

Section 1043(b)

CANA's recommendation that Section 1043(b) be amended to read: "For purposes of this article, "outpatient" means a patient treated in a ~~treatment~~ facility which is not licensed by the State of California as an acute care hospital ~~accredited by the Joint Commission on Health Care Organizations~~ or by an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code(commencing with section 1248). After discussion the board moved to delegate adoption of proposed regulation §1043 to the Executive Officer after subsection (b) is modified, noting that new language should not delete the reference to accreditation by the Joint Commission on Health Care Organization, but should include a reference to define "acute care hospital". Adoption of the language would be contingent upon no negative comments being received following the15-day notice. At a subsequent board meeting, Legal Counsel for the Board advised the Board that the reference to facilities licensed by the Medical Board would be inconsistent with the statute and suggested corrections. The language was modified and noticed from May 16 to June 3, 2005.

No other comments were received during the 45-day comment period or during the January 28, 2005, hearing.

Comments Received During the Period the Modified Text Was Available to the Public.

Modified text was made available to the public from May 16, 2005 until June 3, 2005. The Board did not receive any comments on the modified text.

The Second Modified text was made available to the public from August 23, 2005 until September 9, 2005. The Board did not receive any comments on the second modified text.

Comments made and submitted to the Dental Board of California during the Public Hearing, Feb. 16 1:30pm by Ken Pierson DDS.

First, I would like to thank the Board for their openness and willingness to hear the concerns of stakeholders and for considering potential solutions to clarify and improve issues in the proposed regulation for SB 501. I would also like to thank the Board for their tireless work towards achieving the best outcome for all concerned. It is a difficult task to provide clear and necessary regulation which will improve safety for Californians, while also making sure that there are no conflicts or disparities in authority, clarity and consistency.

I have one concern to which I would like to speak today, and it is the following:

The Board has exempted hospitals but has neglected to exempt accredited Ambulatory Surgery Centers from the proposed regulation.

SB 501 was clearly adopted to increase the safety of sedation in the dental office setting, and in my opinion, this is needed and necessary. What the regulation fails to define or clarify is the difference between the relatively unregulated outpatient dental clinic and the highly regulated outpatient setting of an Accredited Ambulatory Surgery Center. The Board may have not taken into consideration that dental procedures are frequently performed in Accredited Ambulatory Surgery Centers that may or may not have a dentist anesthesiologist on staff. Many times the anesthesia care is provided by contracted anesthesia groups that are made up of MD anesthesiologists and CRNA's who are part of the Centers' Credentialed Medical Staff. It makes no sense that a dentist anesthesiologist or medical anesthesiologist with a permit from the Dental Board of CA be the only anesthesia providers able to provide general anesthesia care to a dental patient in both a hospital and ASC setting. Accredited Ambulatory Surgery Centers are under very strict State and CMS regulation for the outpatient Ambulatory Surgery Center (ASC) setting, just as a hospital is also under very strict State and CMS regulation. For the Boards knowledge and reference, an ASC with CMS deemed status is regulated with CMS Appendix L containing 13 Chapters with 195 Standards with-in those Chapters, for Conditions for Coverage and is surveyed to these standards using this tool every 3 years. Here is a link to Appendix L:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf

Please take note of the specific sections Q-0042 through Q-0064 that have to do with General Anesthesia and surgical services and standards, performed in an ASC.

Clearly, the safety standards required of accredited ASC's far exceed the relatively basic standards established by SB 501 for the dental office setting. My concern is not over the safety regulation but rather over the requirement to have a Dentist Anesthesiologist present if the definition to "outpatient" is not clarified.

I am concerned that if there is no clarification on this issue that this would make it even more challenging to do dental cases in an outpatient ASC setting. This would make access to dental care for some of the most vulnerable subsets of Californians, even more challenging. It has been next to impossible to schedule non-emergent dental cases in the hospital operating rooms during the pandemic, with wait times of over six months in many locales. Utilizing the highly regulated and safe ASC setting has provided access to care for special needs patient and other vulnerable cohorts. If this is overlooked

by the Board during this rule making process, this could unintentionally impose the consequence of eliminating this critical access to dental care for the most vulnerable children and adults.

I appeal to the Board to consider adding language to exempt accredited ambulatory surgery centers in addition to hospitals from this regulation.

Thank you for your time.

Ken Pierson DDS

DENTAL BOARD OF CALIFORNIA
TRANSCRIPT OF PUBLIC HEARING
FEBRUARY 16, 2022

BEFORE THE

DEPARTMENT OF CONSUMER AFFAIRS

DENTAL BOARD OF CALIFORNIA

Public Hearing held before the Department of Consumer Affairs, Dental Board of California, in the Matter of:	)
SB 501, Anesthesia and Sedation	)

TRANSCRIPT OF PROCEEDINGS

Remote hearing held via Webex

Wednesday, February 16, 2022

Reported by:

MARCENA M. MUNGUIA,
CSR No. 10420

Job No.:
35844DCA

BEFORE THE

DEPARTMENT OF CONSUMER AFFAIRS

DENTAL BOARD OF CALIFORNIA

Public Hearing held before the Department of Consumer Affairs, Dental Board of California, in the Matter of:	)
SB 501, Anesthesia and Sedation	)

TRANSCRIPT OF PROCEEDINGS, taken remotely via Webex, commencing at 1:30 p.m. on Wednesday, February 16, 2022, heard before the Department of Consumer Affairs, Dental Board of California, reported by Marcena M. Munguia, CSR No. 10420, a Certified Shorthand Reporter in and for the State of California.

APPEARANCES:

Moderator:	SHELLY JONES Department of Consumer Affairs
DCA Panelists:	DAVID BRUGGEMAN
	JESSICA OLNEY
	KRISTY SCHIELDGE
	SARAH WALLACE
	TARA WELCH

I N D E X

Remote hearing via Webex, Wednesday, February 16, 2022
1:30 p.m.

MS. OLNEY: This online hearing is to consider proposed amendments to Section 1017 of Article 4, section 1021 of Article 6 of Chapter 1, sections 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, and 1043.8 of Article 5, sections 1044, 1044.1, 1044.2, 1044.3, and 1044.5 of Article 5.5 of Chapter 2, and section 1070.8 of Article 2 of Chapter 3, and add section 1043.8.1 of Article 5 and sections 1043.9, 1043.9.1, 1043.9.2 of Article 5.1 of Chapter 2, and repeal section 1044.4 of Article 5.5 of Chapter 2 of Division 10 of the Title -- excuse me -- of Title 16 of the California Code of Regulations of the Dental Board of California's regulations as outlined in the public notice regarding SB 501, Anesthesia and Sedation, which noticed in the California Regulatory Notice Register, was posted on our website and sent to all who have requested such notice.

This hearing is being held pursuant to the procedures set forth in the Administrative Procedure Act.

Today is Wednesday, February 16, 2022 and the time is 1:30.

This meeting is being recorded to capture all

verbal comments made by the public. If you are able to submit your comments in written form via e-mail, to Jessica, which is J-e-s-s-i-c-a, dot Olney, spelled O-l-n-, as in Nancy, -e-y at dca.ca.gov, that would be helpful so that the Dental Board of California is able to capture your comment accurately.

If any written comments have been received on the proposal, they will be made a part of the permanent record.

Please be sure to keep your phone muted until further notice. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed regulatory action or recommends changes that may evolve as a result of this hearing.

If any interested person desires to provide oral testimony, please unmute your phone when prompted. Although not required, we would appreciate it if you gave your name and address and, if you represent an organization, the name of that organization so that we will have a record of all those who comment and can notify you of any modifications to this regulatory proposal.

Please remember to mute your phone again after

making your comment.

It is the desire of the Board that the record of the hearing be clear and intelligible and that the hearing itself be orderly, thus providing all parties with fair and ample opportunity to be heard.

The Board will not respond to any comment at this time but may ask clarifying questions. Responses to timely, relevant and adverse comments will be considered and discussed at this meeting.

The Board will respond to all oral and written comments received in its Final Statement of Reasons, which will be included in the rulemaking file for the proposed regulatory action and which will be posted on our website and be available from the contact person as stated in the original public notice. The original notice, proposed text, and Initial Statement of Reasons are also available on our website and from the same contact person.

A complete copy of the rulemaking file will also be available for review at the Board's office in Sacramento.

After all interested parties have been heard, the issue will stand submitted.

If you wish to be placed on our mailing list, please e-mail the Board at dentalboard@dca.ca.gov.

Include your full name and in the subject line write "SB 501, sedation and anesthesia, mailing list."

We will now move to the moderator, who will explain the process of making comment.

MS. JONES: Thank you. This is the moderator.

And just for the record, we currently have 21 public members in attendance.

To facilitate public comment for this hearing, we will be using the Webex Question and Answer feature. Members of the public can indicate that they would like to make a comment by locating the Q&A icon on your screen, which looks like a question mark inside of a scare. When you click on this icon, it will open a text box and in that text box you will type the word "comment" and submit that to the host.

Please note that the Question and Answer feature is being used only as a means for members of the public to represent that they would like to make a verbal comment. This is not a means to ask questions of the moderator or staff of the Board. Such inquiries submitted using this feature will not be answered.

When making your comment, please make sure the comment is directed to the host in the dropdown.

For those members of the public who have called in to the meeting, you may utilize the Raise Hand feature

to indicate you would like to make a comment by dialing star 3. We do ask that once you have made your comment, you dial star 3 again to lower your hand.

We will be taking comments in the order that the requests are received. I will call on the first individual and give you permission to unmute your microphone. To do this, you will see a pop-up appear at your end and you will need to click on the Unmute Me button to open your microphone.

Each individual will have three minutes to make their comments, for which I will provide a 30-second reminder before your time expires.

At the conclusion of the three minutes, your microphone will be muted and we will move on to the next member of the public who has a comment.

While you are free to express criticism or negative views, for the sake of the members of the public participating on the call, please do not use profane language when making public comments.

With that, I will turn it back over to Board staff.

MS. OLNEY: Thank you, Moderator.

Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin?

And, Moderator, if we can open the Q&A for any questions on procedures.

MS. JONES: The Q&A has been opened.

I will check in with Mary Wilson, who has her hand raised.

Mary, I've sent in a request to unmute your microphone. I just want to confirm whether your question is regarding procedures or if it is to make a comment on the record. We are currently just asking if there are questions for procedures at this point in time.

Okay. I believe she may be indicating to make a comment. I do not see any procedural requests at this time.

MS. OLNEY: Thank you, Moderator.

If there are no procedural questions, we will consider the Board's proposed regulatory actions relative to the specified section. Those persons interested in testifying today will be called to testify one at a time.

Are there any comments from the public? If you would like to make a comment on the proposed regulation, type "I would like to make a comment" in the Q&A answer box, which is located in the right-hand side of your screen.

We will give a moment and I will remind you that when you testify, at your discretion, please clearly

identify yourself and any organization you represent. Speak loudly enough so that your testimony can be heard and recorded.

It is not necessary to repeat testimony as previous commenters. It is sufficient to merely indicate that your agreement with the comment was made.

When you testify, please identify the specific portion of the regulation you are addressing.

Each individual will have three minutes to make their comments. At the conclusion of the three minutes, the individual's microphone will be muted and we will move on to the next member of the public who has a comment.

If you have submitted written comments, please do not read them. Please note that the Question & Answer feature is being used only as a means for the members of the public to represent that they would like to make a verbal comment. This is not a means to ask questions of the moderator or Board staff. Such inquiries submitted using this feature will not be answered.

Moderator, if we can open the Q&A for public comment.

MS. JONES: Thank you. The Q&A is open.

Our first comment today comes from Jeanne Vance.

Jeanne, I sent the request to unmute your

microphone.

MS. VANCE: Thank you very much. This is Jeanne Vance.

I am an attorney that practices in the area of healthcare. I'm from the Sacramento-based law firm of Weintraub Tobin. I've been practicing for 27 years and I would like to offer my thoughts on the proposed regulation.

The content of the proposed regulation as a whole, I am not raising any objection. What I am raising objections to is that it needs to make clear that these new regulations will apply to dental offices and not to certified ambulatory surgery centers, and I think that the way that the proposed regulation is written is confusing about that.

The certified ambulatory surgery centers were created as an alternative to hospitals, general acute care hospitals, as a less expensive, more efficient method of delivering the kind of care that you could get in an acute care hospital at a less expensive price point with a very similar complication rate -- I did provide some written support for that in my written comments -- and they have been very successful and have been a very favored business model in terms of federal reimbursement, et cetera, and the reason is because they just do a

really good job at providing services that would otherwise be delivered in a hospital, in a much less invasive setting.

The surgery centers already have extensive regulations in place that they have to comply with to provide anesthesia. I provided 178 pages of federal regulations that are applied by accrediting bodies and the federal government, most of which concerns how anesthesia is provided, their ongoing quality reviews, inspections, prelicensure surveys, et cetera. And so the only thing that would be done by imposing the Dental Board regulations would be to require them to get -- to provide staff that, frankly, are not very common in California, and --

MS. JONES: 30 seconds.

MS. VANCE: -- so we are well aware that there is a staffing shortage here and I would hate to see this really good delivery model be impaired in their operations without real benefit, because the regulations they're already under I think do a better job at regulating anesthesia in these surgery centers.

I provided some amendments in my written comments that I think would fix this and I ask you to consider those.

MS. JONES: Thank you.

Our next comment comes from Dr. Bruce Whitcher.

Dr. Whitcher, I've sent the request to unmute your microphone.

DR. WHITCHER: Thank you.

This is Dr. Bruce Whitcher, representing California Dental Association, and I believe you have my address, so I won't repeat that here.

We did submit written comments and I'll simply summarize these very briefly.

First of all, on page 49, I notice that the fee information is missing from the application for the pediatric endorsement form and we would appreciate it if that were added, because you may have difficulty charging the fee for the endorsement without that information being there.

Other missing information is also the certification of training for the pediatric endorsement for the moderate sedation permit also does not appear to be on Form PE 1, also on page 49. It would be a simple matter to add the certification of training for moderate sedation to that.

And thirdly, the certification of training form for the application for the use of oral conscious sedation for adults is also missing in the draft regulations. There were some previous forms, OCS 2 and

OCS 3, that were previously used that probably could be revised and just inserted into the package for that purpose.

On a more technical note, we would like to see a criteria for Board-approved training in pediatric life support and airway management in addition to PALS. PALS is called out as the required training; however, there is the option for a Board-approved training in pediatric life support and airway management, and we would like to see these Board-approved criteria developed and made a part of the draft regulations, and the details again are in our written comments.

Finally, I would agree with some of what the previous commenter said, in that the definition of "outpatient facility" would best mirror what's in the Health and Safety Code 1248 and 1248.1, which defines outpatient settings in a more standardized format, and I think it would be useful if the Board would clarify whether a dentist may order the administration of deep sedation or general anesthesia within their scope of practice in an outpatient facility as described in 1248.15. Again, it's not clear to me whether this is required or not, so that would be helpful.

Finally, we would like to see the Dental Board define some equivalency standards for training in

pediatric moderate sedation for the pediatric endorsement. Basically, you can qualify for the endorsement through a pediatric dental --

MS. JONES: 30 seconds.

DR. WHITCHER: -- however, that requires 25 cases instead of 20 cases. So they may, in fact, be equivalent. So the Board -- so we would appreciate it if the Board would look at that.

So that concludes my comments. Thank you.

MS. JONES: Thank you.

Our next comment comes from Bryce Docherty.

Bryce, I've sent the request to unmute your microphone.

MR. DOCHERTY: Can folks you hear me okay?

MS. JONES: We Can.

MR. DOCHERTY: Okay. Great.

My name is Bryce Docherty. I represent the California Ambulatory Surgery Association. We're the statewide association that represents State licensed, accredited and Medicare-certified ASCs. We have about over 400 members. There's approximately 8- to 900 Medicare-certified ASCs in the state.

We share similar comments with the first speaker and we've submitted comments yesterday that speak to these issues. We have raised five specific areas within

these regulations that need to be amended, one section in existing regulations that we suggest needs to be changed and one provision in the existing statutory language for SB 501 that needs to be preamended.

The premise of our comments is the fact that the Dental Board of California has no statutory jurisdiction over the regulation of an ambulatory surgery center. ASCs are allowed to perform procedures where patients are losing all forms of lifesaving motor skills based on the level of anesthesia if they meet one of three criteria.

First, they can be licensed by the Department of Public Health as a surgical clinic, pursuant to Health and Safety Code section 1204(b)(1) or, two, they can be accredited as an outpatient setting by one of the five or six accrediting bodies approved by the Medical Board of California pursuant to Health and Safety Code section 1248 or, three, they have the choice to also be certified by the Medicare program as an ambulatory surgery surgical center pursuant to CMS requirements.

Therefore, the Dental Board only has authority over the dentists that are practicing in these facilities. The existing statutes only exempt a facility, an outpatient setting, that is accredited by the Joint Commission or an acute care hospital license under 1250 of the Health and Safety Code.

We would recommend changing the definition of "outpatient setting" to specifically include all three of the types of facilities that I already enumerated.

And furthermore, we are -- furthermore, we are asking for those -- that reference to be consistent throughout the regulations, and I'm happy to answer any questions, but most of our comments speak to some of our suggested changes in that regard. Thank you.

MS. JONES: Thank you.

Our next comment comes from Monica Wilson -- I mean, sorry, Monica Miller, and then it will be Mary Wilson.

Monica, I have sent the request to unmute your microphone.

MS. MILLER: I'm Monica Miller, representing the California Association of Nurse Anesthetists.

Thank you so much to you and your staff for all the time you've given us, but we also share the concerns previously stated with regard to how ASCs are being audited by the Dental Board of California.

We have formally submitted our comments from our lawyer, Mayer Brown out of Los Angeles. We know that your staff has a lot of work to do. We look forward to the ongoing conversation in an effort to try and rectify this problem.

These ASCs are so critical to patient access and ensuring that our patients are getting the care that they need and the dental anesthesia that they need from the appropriate provider.

We continue to work with your staff. We appreciate your time today. We appreciate the fact that you put on this hearing for us and look forward to ongoing conversations.

Thank you so much and have a great day.

MS. JONES: And our next comment comes from Mary Wilson.

Mary, I've sent the request to unmute your microphone.

DR. WILSON: Good afternoon. My name is Dr. MaryAnn Wilson. I'm a GNP preparer CRNA and I'd like to speak -- I'd like to thank the Board on behalf of the children of Indio as well as San Bernardino, Riverside, and Imperial Counties. I want to thank the Board for this opportunity to speak at this public hearing.

My specific concern today is, like the previous speakers have commented, on the ASCs.

Business Code Division 2, Chapter 6, Article 2827 where it says, "The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care

facility's administration," my request is that the acute care facility language and interpretation to include outpatient surgery centers.

The surgery center in which I serve in Indio is 23 miles east of Palm Springs and 128 miles east of Los Angeles. There are -- 27 percent of the population is under the age of 18 and the demographics for the city is 68 percent Hispanic. There's definitely some healthcare disparencies going on if this were to go forward and we, the ASCs, weren't able to function like they have been in the past with the CRNAs able to give anesthesia at the centers.

Healthy People 2020 defines the health disparency as a particular type of health difference between social and economic and environmental disadvantages. So one of the critical components of operating these surgery centers is that the high-quality anesthesia providers needed to address these significant health and dental disparency. The way that we bridge that gap is with CRNAs, MDA anesthesiologists, and dental anesthesiologists working together side by side in operating rooms. So I'm asking on behalf of the families and children of the three counties in which I have the privilege to serve that they have health equality that they also deserve.

So my two recommendations is to modify the SB 501, is that the accredited Medi-Cal certified surgery centers be exempt from the definition of "outpatient" and that certified ambulatory surgery centers be included with the acute care facilities in section 2827 in reference to CRNAs.

Thank you so much for your time.

(Pause in the proceedings)

MS. JONES: We have a request for comment from Michael Warda.

Michael, I've sent a request to unmute your microphone. As a reminder, you'll have three minutes.

MR. WARDA: My name is Mike Warda. I'm an attorney here in California. I've been practicing since about 1995.

I'm also calling to enter comment on the exemption of ASCs or to make it clear that they're exempt from the regulations applying to dental offices. Right now, these ASCs play a critical role in the treatment of children and they're primarily from minority populations, and tens of thousands of kids are getting treatment, sometimes for the first time in years, at these ASCs. They come in in extreme pain and generally have, like I said, never had dental treatments before.

If somehow ASCs are limited from providing this

treatment, you're going to see a rush on emergency rooms where they're there prescribed for pain medication and then sent to dental offices where most dental offices are not properly equipped or simply can't provide the service that they need.

Dental offices today refer tens of thousands of cases to the ASCs. The introductory language for the statutory scheme of SB 501 makes a point to ask the health agency to protect minority populations and in these cases -- in some of the cases at these ASCs, 80 to 100 percent of the patients are from the minority communities that are being serviced through the Denti-Cal program. In addition to that, you see folks that are developmentally challenged that are not able to go to a dental office and get service at these locations.

As some comments were made, these ASCs are licensed by the Department of Public Health in some cases and in other cases they're certified by Medicare.

So I think that what we're looking for in this case is just clarification in the language that indicates that just like acute care hospitals are exempted from these regulations, so would be ASCs that are properly certified.

Thanks very much for your time.

MS. JONES: Thank you.

And I do see that our court reporter has her hand raised. Marcena, did you have a question?

THE REPORTER: No. There was just a gap I was questioning. It's fine.

MS. JONES: Okay. Thank you.

Our next comment comes from Ken.

Ken, I've sent the request to unmute your microphone.

DR. PETERSON: Ken Peterson. I don't represent any organization. I'm just a dentist member of -- that has a license through the Dental Board of California.

First I'd like to thank the Board for their openness and willingness to work to hear the concerns of stakeholders and for considering potential solutions to clarify and improve issues in the proposed regulation for SB 501.

I'd also like to thank the Board for their tireless work towards achieving the best outcome for all concerned. It is a difficult task to provide clear and necessary regulation which will improve safety for Californians while also making sure that there are no conflicts or disparities in authority, clarity or consistency.

I have one concern to which I'd like to speak today and that is the following: The Board has exempted

hospitals but has neglected to exempt accredited ambulatory surgery centers from the proposed regulation.

SB 501 was clearly adopted to increase the safety of sedation in the dental office setting and, in my opinion, this is needed and necessary. What the regulation fails to define or clarify is the difference between the relative un- -- relatively unregulated outpatient dental clinic and the highly regulated outpatient setting of an accredited ambulatory surgery center.

The Board may not have taken into consideration that dental procedures are frequently performed in accredited ambulatory surgery centers that may or may not have a dentist anesthesiologist on staff. Many times the anesthesia care is provided by contracted groups that are made up of MD anesthesiologists or CRNAs who are part of the center's credentialed medical staff.

It makes no sense that a dentist anesthesiologist or a medical anesthesiologist with a permit from the Dental Board of California be the only anesthesia providers able to provide general anesthesia to a dental patient in both a hospital and ASC setting.

Accredited ambulatory surgery centers are under very strict State and CMS regulation for the outpatient ambulatory surgery center setting, just as a hospital is

also under strict regulation by State and CMS regs.

For the Board's knowledge and reference, an ASC with deemed -- CMS-deemed status is regulated with CMS Appendix L and is surveyed to the surgery centers --

MS. JONES: 30 seconds.

DR. PETERSON: -- using this tool every three years.

I am extremely concerned that if there is no clarification on this issue that it will be even more difficult to -- for dental cases in an ASC setting, which would make access to care even -- for the most vulnerable subset of the population even harder. It has been next to impossible to schedule dental cases in hospital operating rooms during the pandemic and it would be even more challenging if the ASCs are not available.

I ask the Board -- I appeal to the Board to consider adding language to exempt accredited ambulatory surgery centers, like hospitals, from these regulations.

MS. JONES: Your time has expired.

(Pause in the proceedings)

MS. JONES: This is the moderator. We have no additional requests for comment at this time. We will be leaving the record open for a little while in case other members join.

(Pause in the proceedings)

MS. OLNEY: Thank you for the comments received. We

will leave this public hearing open and if no additional comments are received, we will close the comment period at 2:30 p.m. Thank you.

(Pause in the proceedings)

MS. JONES: I'd just like to let our attendees know that the meeting will be closing at 2:30. If anyone has any additional comments, please follow the instructions.

MS. OLNEY: I'd also like to clarify that comments received will be considered and acted on by the Board at a future noticed Board meeting.

It is now 2:30. We thank everyone for their participation and comments. This ends this regulatory hearing. Thank you.

(Hearing concluded at 2:30 p.m.)

REPORTER'S CERTIFICATION

I, the undersigned, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were duly sworn; that a record of the proceedings was made by me using machine shorthand, which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a federal case, before completion of the proceedings, review of the transcript was not requested.

I further certify I am neither financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: February 22, 2022

Marcena M. Munguia, CSR No. 10420
Certified Shorthand Reporter
For The State Of California

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. DENTAL BOARD OF CALIFORNIA

MODIFIED TEXT
SB 501 (2018) Anesthesia and Sedation

Legend: For the originally proposed language:
Added text is indicated with an underline.Omitted text is indicated by (* * * *) Deleted text is indicated by ~~strikeout~~.

Modifications to the originally proposed regulatory language are shown in double underline for new text and double ~~strikethrough~~ for deleted text.

Amend section 1021 of Article 6 of Chapter 1, sections 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, and 1043.8 of Article 5, sections 1044, 1044.1, 1044.2, 1044.3, and 1044.5 of Article 5.5 of Chapter 2, and section 1070.8 of Article 2 of Chapter 3, and add section 1017.1 of Article 4 of Chapter 1, section 1043.8.1 of Article 5 and sections 1043.9, 1043.9.1, and 1043.9.2 of Article 5.1 of Chapter 2~~, and repeal section 1044.4 of Article 5.5 of Chapter 2~~ of Division 10 of Title 16 of the California Code of Regulations to read as follows:

Chapter 1. General Provisions Applicable to All Licensees

Article 4 Continuing Education

§ 1017.1. ~~Processing Times. [Repealed]~~ Continued Competency Requirements for Renewal of Permits with Pediatric Endorsements.

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

(b) As a condition of renewal, each dentist licensee who holds a moderate sedation permit with a pediatric endorsement shall confirm to the Board in writing the following as part of the permit renewal requirements in Section 1043.8 ("application"):

(1) Whether the licensee completed at least twenty (20) cases of moderate sedation for children under thirteen years of age in the 24-month time period immediately preceding application for their current permit renewal either independently and/or under the direct supervision of another permit holder;

(2) Whether the licensee completed at least twenty (20) cases of moderate sedation for children under seven years of age in the 24-month time period immediately preceding application for their current permit renewal either independently and/or under the direct supervision of another permit holder, and;

(3) If applicable, if the licensee lacks sufficient cases, whether the licensee is administering moderate sedation to patients under seven years of age only under the direct supervision of a permit holder who meets the qualifications of 1647.3 of the Code.

Note: Authority cited: Section 1614, Business and Professions Code
Reference: Sections 1646.2, and 1647.3, Business and Professions Code.

Article 6. Fees

§ 1021. Examination, Permit and License Fees for Dentists.

The following fees are set for dentist examination and licensure by the board, and for other licensee, registrant or applicant types specified below**:

(a) Initial application for those applicants qualifying pursuant to Section 1632(c)(2) of the Business and Professions Code (the Code)	$400
(b) Initial application for those applicants qualifying pursuant to Section 1634.1 of the Code	$800
(c) Initial application for those applicants qualifying pursuant to Section 1632(c)(1) of the Code	$400
(d) Initial application fee for those applicants applying pursuant to Section 1635.5 of the Code	$525
(e) Initial license	$650*
(f) Biennial license renewal fee	$650
(g) Biennial license renewal fee for those qualifying pursuant to Section 1716.1 of the ~~c~~Code shall be one half of the renewal fee prescribed by subsection (f).	
(h) Delinquency fee -license renewal - The delinquency fee for license renewal shall be the amount prescribed by section 1724(f) of the ~~c~~Code.	
(i) Substitute certificate	$50
(j) Application for an A~~a~~dditional O~~o~~ffice P~~p~~ermit	$350

(k) Biennial renewal of Aadditional Ooffice Ppermit	$250
(l) Late change of practice registration	$50
(m) Fictitious Nname Ppermit The fee prescribed by Section 1724.5 of the Code	
(n) Fictitious Nname renewal	$325
(o) Delinquency fee -Ffictitious Nname renewal. The delinquency fee for fictitious name permits shall be one-half of the Ffictitious Nname Ppermit renewal fee	
(p) Continuing Eeducation Rregistered Pprovider fee	$410
(q) Application for General Aanesthesia or conscious Moderate Ssedation Ppermit	$500524
(r) Oral Conscious Sedation Certificate Renewal Application for Pediatric Minimal Sedation Permit	$168459
(s) General Aanesthesia (for dentist and physician licensees) or conscious Moderate Ssedation Ppermit renewal fee	$325
(t) Pediatric Minimal Sedation Permit renewal fee	$182
(tu) General Aanesthesia or conscious Moderate Sedation Oon-site Iinspection and Eevaluation fee	$2,000
(uv) Application for a Special Permit	$1,000
(vw) Special Permit Renewal	$125
(wx) Initial Application for an Elective Facial Cosmetic Surgery Permit	$850
(xy) Elective Facial Cosmetic Surgery Permit Renewal	$800
(yz) Application for an Oral and Maxillofacial Surgery Permit	$500
(zaa) Oral and Maxillofacial Surgery Permit Renewal	$650
(aab) Continuing Education Registered Provider Renewal	$325
(abc) License Certification	$50
(acd) Application for Law and Ethics Examination	$125

(ad~~d~~e) Application for Adult ~~or minor~~ Oral Conscious Sedation Certificate	$~~368~~459
(af) Adult Oral Conscious Sedation Certificate Renewal	$168
(ag) Application for Pediatric Endorsement for General Anesthesia Permit (for dentist and physician licensees)	$532
(ah) Application for Pediatric Endorsement for Moderate Sedation Permit	$532

Fee pro-rated based on applicant's birth date.

**Examination, licensure, and permit fees for dentistry may not all be included in this section, and may appear in the ~~Business and Professions~~ Code.

Note: Authority cited: Sections 1614, 1635.5, 1634.2(c), 1724 and 1724.5, Business and Professions Code. Reference: Sections 1632, 1634.1, 1646.2, 1646.6, 1647.3, 1647.8, ~~1647.12,~~ 1647.~~15~~20, 1647.23, 1647.32, 1647.33, 1715, 1716.1, 1718.3, 1724 and 1724.5, Business and Professions Code.

Chapter 2. Dentists

Article 5. General Anesthesia and (~~Moderate~~) ~~Conscious~~ Sedation

§ 1043. Definitions.

(a) For purposes of this article, “direct supervision” of deep sedation or general anesthesia means the permittee is in the immediate presence of a patient while deep sedation or general anesthesia is being administered to that patient and that the permittee or a member of the permittee's staff directly monitors the patient at all times.

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

(c) For purposes of section 1682(a) of the ~~c~~Code:

(1) a patient under deep sedation or general anesthesia shall be considered “sedated” for that period of time beginning with the first administration of deep sedation or general anesthetic agents until that time when the patient is again conscious with a full return of protective reflexes, including the ability to respond purposely to physical stimulation and/or verbal command, when no additional agents will be administered, the dental procedures have been completed, and after the

maximum effects of all agents have been experienced by the patient;

(2) a patient under ~~conscious~~moderate sedation shall be considered "sedated" for that period of time beginning with the first administration of ~~conscious~~moderate sedation agents until that time when no additional agents will be administered, the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient.

(d) For purposes of ~~s~~Section 1682(b) of the ~~c~~Code, a patient shall be deemed to be "recovering from" ~~conscious~~moderate sedation, deep sedation, or general anesthesia from the time the patient is no longer "sedated" as that term is defined in subsection (c) above until the dentist has evaluated the patient and has determined the patient is responsive, alert, has stable vital signs and is ambulatory and/or capable of being safely transported.

(e) For purposes of this article, "applicant" refers to applicants without permits, as well as permit holders subject to re-evaluation.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.1 and 1682, Business and Professions Code.

§ 1043.1. Permit Application Requirements.

(a) A licensed dentist does not need a general anesthesia or ~~conscious~~ moderate sedation permit if the deep sedation, general anesthesia, or ~~conscious~~ moderate sedation administered in that dentist's office is directly administered by a licensed dentist or physician and surgeon who possesses a general anesthesia or ~~conscious~~ moderate sedation permit, whichever is applicable to the type of anesthesia or sedation services being provided.

(b) For the purposes of Sections 1646.2 and 1646.9 of the Code, ~~A~~an applicant for a permit to administer deep sedation or general anesthesia ~~or order the administration of general anesthesia by a nurse anesthetist must be a licensed dentist in California who:~~ shall submit a completed "Application for General Anesthesia Permit" Form GAP-1 (New 05/2021) to the Board, which is hereby incorporated by reference. The application shall be accompanied by the application fee set forth in Section 1021.

(1) ~~Has completed a residency program in general anesthesia of not less than one calendar year, that is approved by the board; or~~
(2) ~~Has completed a graduate program in oral and maxillofacial surgery which has been approved by the Commission on Dental Accreditation.~~

(c) If the applicant wishes to administer or order the administration of deep sedation or general anesthesia to patients under seven years of age, the applicant shall apply for a pediatric endorsement to their general anesthesia permit as set forth in Section 1043.8.1 and receive approval from the Board.

(~~c~~d) For the purposes of Section 1647.2 and 1647.3 of the Code, ~~A~~an applicant for a permit to administer or order the administration of ~~conscious~~ moderate sedation ~~must be a licensed dentist in California who meets the requirements set forth in section 1647.3 of the code~~shall submit a completed "Application for Moderate Sedation Permit" Form MSP-1 (New 05/2021), which is hereby incorporated by reference. The application shall be accompanied by the following:

(1) A completed "Certification of Moderate Sedation Training" Form MSP-2 (New 05/2021), which is hereby incorporated by reference; and

(2) The application fee set forth in Section 1021.

(e) If the applicant wishes to administer or order the administration of moderate sedation to patients under thirteen years of age, the applicant shall apply for a pediatric endorsement to their moderate sedation permit as set forth in Section 1043.8.1 and receive approval from the Board.

~~(d) The processing times for a general anesthesia or conscious sedation permit are set forth in section 1061.~~

Note: Authority cited: Sections 1614 and 1646.2, Business and Professions Code. Reference: Sections 1646.1, 1646.2, 1646.9, 1647.2, 1647.3 and 2827, Business and Professions Code.

§ 1043.2. Composition of Onsite Inspection and Evaluation Teams.

(a) An evaluation team shall 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.

(b) The evaluators must meet one of the criteria in ~~subdivision~~subsection (b) of ~~s~~Section 1043.1 for general anesthesia or the criteria in ~~s~~Section 1647.3 of the ~~c~~Code for ~~conscious~~ moderate sedation and must have utilized general anesthesia, deep sedation, or ~~conscious~~ moderate sedation, whichever is applicable, in a dental practice setting for a minimum of three years immediately preceding their application to be an evaluator, exclusive of any general anesthesia, deep sedation, or ~~conscious~~ moderate sedation training.

(c) At least one of the evaluators must have experience in evaluation of dentists administering general anesthesia, deep sedation, or ~~conscious~~ moderate sedation. At least one member of the team must have substantial experience in the administration of the method of delivery of general anesthesia, deep sedation, or ~~conscious~~ moderate used by the dentist being evaluated.

(d) Evaluators shall 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.

(~~d~~e) The board may appoint a licensee member of the board to serve as a consultant at any evaluation.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, 1646.9, Business and Professions Code.

§ 1043.3. Onsite Inspections.

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

(a) Office Facilities and Equipment. 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. The following office facilities and equipment shall be available ~~and shall be maintained in good operating condition~~:

(1) An operating theatre large enough to adequately accommodate the patient on a table or in an operating chair and permit an operating team consisting of at least three individuals to freely move about the patient.

(2) An operating table or chair which permits the patient to be positioned so the operating team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.

(3) A lighting system which 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.

(4) Suction equipment which permits aspiration of the oral and pharyngeal cavities. A backup suction device which can operate at the time of general power failure must also be available.

(5) An oxygen delivery system with adequate full face 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 which can operate at the time of general power failure.

(6) A recovery area that has available oxygen, adequate lighting, suction, and electrical outlets. The recovery area can be the operating theatre.

(7) Ancillary equipment:

(A) Laryngoscope complete with adequate selection of blades and spare batteries and bulb. (This equipment is not required for ~~conscious~~ moderate sedation.)

(B) Endotracheal tubes and appropriate connectors. (This equipment is not required for ~~conscious~~ moderate sedation.)

(C) Emergency airway equipment (oral airways, laryngeal mask airways or combitubes, cricothyrotomy device).

(D) Tonsillar or pharyngeal type suction tip adaptable to all office outlets.

(E) Endotracheal tube forceps. (This equipment is not required for ~~conscious~~ moderate sedation.)

(F) Sphygmomanometer and stethoscope.

(G) Electrocardioscope and defibrillator. (This equipment is not required for ~~conscious~~ moderate sedation.)

(H) Adequate equipment for the establishment of an intravenous infusion.

(I) Precordial/pretracheal stethoscope.

(J) Pulse oximeter.

(K) Capnograph and temperature device. ~~A capnograph and temperature measuring device are required for the intubated patient receiving general anesthesia. (This equipment is not required for conscious sedation.)~~ Patients receiving moderate sedation, deep sedation, or general anesthesia shall have ventilation continuously monitored during the procedure by two of the following three methods:

(i) Auscultation of breath sounds using a precordial stethoscope.

(ii) Monitoring for the presence of exhaled carbon dioxide with capnography.

(iii) Verbal communication with a patient under moderate sedation. This method shall not be used for a patient under deep sedation or general anesthesia.

(b) Records. The following records shall be maintained:

(1) Adequate medical history and physical evaluation records updated prior to each administration of ~~general anesthesia or conscious sedation~~ moderate sedation, deep sedation, or general anesthesia. Such records shall include, but are not limited to the recording of the age, sex, weight, physical status (American Society of Anesthesiologists Classification), medication use, any known or suspected medicallycompromising conditions, rationale for sedation of the patient, and visual examination of the airway, and for general anesthesia or deep sedation only, auscultation of the heart and lungs ~~as medically required~~.

(2) Moderate sedation, deep sedation, and/or general anesthesia ~~General Anesthesia and/or conscious sedation~~ records, which shall include a time-oriented record with preoperative, multiple ~~interaoperative~~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.

(3) 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.

(~~3~~4) Written informed consent of the patient or, as appropriate, patient's conservator, or the informed consent of a person authorized to give such consent for the patient, or if the patient is a minor, his or her parent or guardian, pursuant to Section 1682(e) of the Code.

(c) Drugs. Emergency drugs of the following types shall be available:

(1) Epinephrine

(2) Vasopressor (other than epinephrine)

(3) Bronchodilator

(4) Muscle relaxant (This is not required for ~~conscious~~ moderate sedation.)

(5) Intravenous medication for treatment of cardiopulmonary arrest (This is not required for ~~conscious~~ moderate sedation.)

(6) Appropriate drug antagonist

(7) Antihistaminic

(8) Anticholinergic

(9) Antiarrhythmic (This is not required for ~~conscious~~ moderate sedation.)

(10) Coronary artery vasodilator

(11) Antihypertensive (This is not required for ~~conscious~~ moderate sedation.)

(12) Anticonvulsant

(13) Oxygen

(14) 50% dextrose or other antihypoglycemic

(d) Prior to an onsite inspection and evaluation, the dentist shall provide a complete list of his/her emergency medications to the evaluator.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.2, 1646.3, 1647.3 and 1647.6, Business and Professions Code.

§ 1043.4. Evaluation Standards.

The evaluation of an applicant for a permit shall consist of two parts:

(a) Demonstration of a General Anesthesia or Deep Sedation. A dental procedure utilizing general anesthesia or deep sedation administered by the applicant must be observed and evaluated. Any anesthesia or deep sedation technique that is routinely employed can be demonstrated. The patient shall be monitored while anesthetized or sedated and during recovery from anesthesia or sedation in the manner prescribed by ~~s~~Section 1682 of the ~~c~~Code.

The applicant for a permit must demonstrate that he or she has knowledge of the uses of the equipment required by ~~s~~Section 1043.3(a) and is capable of using that equipment.

(b) Demonstration of a ~~Conscious~~Moderate Sedation. A dental procedure utilizing ~~conscious~~ moderate sedation administered by the applicant must be observed and evaluated. Any ~~conscious~~ moderate sedation technique that is routinely employed can be demonstrated. The patient shall be monitored while sedated and during recovery from sedation in the manner prescribed by ~~s~~Section 1682 of the ~~c~~Code. The applicant

for a permit must demonstrate that he or she has knowledge of the uses of the equipment required by ~~s~~Section 1043.3(a) and is capable of using that equipment.

(c) Simulated Emergencies. Knowledge of and a method of treatment must be physically demonstrated by the dentist and his or her operating team for the following emergencies:

(1) Airway obstruction

(2) Bronchospasm

(3) Emesis and aspiration of foreign material under anesthesia

(4) Angina pectoris

(5) Myocardial infarction

(6) Hypotension

(7) Hypertension

(8) Cardiac arrest

(9) Allergic reaction

(10) Convulsions

(11) Hypoglycemia

(12) Syncope

(13) Respiratory depression

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, Business and Professions Code.

§ 1043.5. Cancellation of an Onsite Inspection and Evaluation.

(a) Whenever a ~~conscious~~ moderate sedation or general anesthesia permittee or applicant cancels an onsite inspection and evaluation, that permittee or applicant shall provide the board with a written reason for the cancellation. If the first cancellation occurs 14 calendar days or more before the date of the scheduled inspection and evaluation, the fee paid shall be applied toward the next scheduled inspection and evaluation. If the cancellation occurs less than 14 calendar days before the scheduled inspection and evaluation, the fee shall be forfeited and a new fee shall be paid before the inspection and evaluation will be rescheduled.

(b) If a permittee or applicant cancels the inspection and evaluation for a second time, all fees are forfeited and the permit shall be automatically suspended or denied unless a new fee has been paid and an onsite inspection and evaluation has been completed within 30 calendar days from the date of the second cancellation.

(c) If a permittee or applicant cancels the scheduled onsite inspection and evaluation for a third time, all fees are forfeited and that cancellation shall be deemed a refusal to submit to an inspection and evaluation, and in accordance with Sections 1646.4 and 1647.7 of the ~~c~~Code, the permit shall be automatically revoked or denied as of the date of the third cancellation.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1646.7, Business and Professions Code.

§ 1043.6. Grading of Inspection and Evaluation.

(a) The inspection and evaluation shall be graded on a pass/fail system. The grade shall be determined by the board, based upon a recommendation of the evaluators, who shall make independent evaluations and recommendations.

(b) The evaluation team shall recommend one of the following grades:

(1) Passed Evaluation. Permit holder met all required components of the onsite inspection and evaluation as provided in sections 1043.3 and 1043.4; or

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

(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 provided in subsection (b)(2) of this section.

(b~~c~~) ~~An applicant who has failed the evaluation may appeal that decision to the board and request a reevaluation. This appeal must be made in writing to the board stating the grounds for the appeal within thirty (30) days after the date on which the evaluation~~

~~results were mailed. However,~~ pPursuant to ~~s~~Sections 1646.4(a), 1646.9(d) and 1647.7(a) of the ~~c~~Code, the permit of any applicant who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the applicant of the failure unless, within that time period, the applicant has retaken and passed an onsite inspection and evaluation.
~~Upon receipt of the appeal request and an additional evaluation fee, the board will schedule an independent reevaluation of the appellant.~~ If an applicant has failed two evaluations, the board will decide the matter and may grant or deny a permit or request further evaluation of the appellant with a board member or other board appointed representative being present. The applicant must successfully complete remedial education in a subject within the scope of the onsite inspection and evaluation as determined by the Board prior to being ~~retested~~ reevaluated if a third onsite inspection and evaluation is granted or prior to the issuance of a new permit.

(~~c~~d) An applicant who has failed the inspection and evaluation solely on the basis of a failure to demonstrate knowledge and ability in recognition and treatment of any or all of the simulated emergencies may be reevaluated only on the simulated emergencies provided the reevaluation is within 30 days.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4, 1646.9, and 1647.7, Business and Professions Code.

§ 1043.7. Manner of Giving Notice of Evaluation.

Upon receipt of either an application for a general anesthesia permit or a ~~conscious~~ moderate sedation permit or where the board determines in any other case that there shall be an onsite inspection and evaluation, the board shall determine the date and time of such evaluation and shall so inform the dentist.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.4 and 1647.7, Business and Professions Code.

§ 1043.8. Renewal.

A general anesthesia or ~~conscious~~ moderate sedation permit shall be renewed biennially upon certification by the permit holder that he/she has met all applicable continuing education requirements in section 1017 and continuing competency requirements for the particular permit in section 1017.1, payment of the required fee in section 1021 and if required, successful completion of an onsite inspection and evaluation.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.1, 1646.2, 1646.5, 1646.6, 1647.2, 1647.3, 1647.5 and 1647.8, Business and Professions Code.

§ 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.

(a) For the purposes of Sections 1646.2(c) and 1646.9 of the Code, submission of a completed application to the Board for a pediatric endorsement for a general anesthesia permit shall include the following information and documents:

(1) Name, mailing address or address of record, physical address, dental or medical license number, and applicant's general anesthesia permit number, if any;
(2) 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;
(3) A completed Form PE-1 (05/2021) "Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement," which is hereby incorporated by reference;
(4) A certificate or other documentary evidence 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);
(5) An application fee as set forth in section 1021; and,
(6) A certification, under penalty of perjury, by the applicant that the information on the application is true and correct.

(b) For the purpose of Section 1647.3(d) of the Code, submission of a completed application to the Board for a pediatric endorsement for a moderate sedation permit for patients under thirteen years of age shall include the following information and documents:

(1) Name, mailing address or address of record, physical address, dental license number, and applicant's moderate sedation permit number, if any;
(2) A certificate of completion or other documentary evidence showing completion of a residency training program as required by Section 1647.3 of the Code;
(3) A completed Form PE-1 as provided in this section;
(4) 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);
(~~6~~5An application fee as set forth in section 1021; and,
(~~7~~6) A certification, under penalty of perjury, by the applicant that the informationon the application is true and correct.

~~(c) 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.~~

(~~d~~c) Upon request by the Board in any investigation of the information provided on FormPE-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.

(~~e~~d) Applicants shall submit legible copies of the information required by this section withpediatric patient identifying information redacted.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 27, 108, 1611.5, 1646.1, 1646.2, 1647.2 and 1647.3, 1646.9, Business and Professions Code.

Article 5.1. Pediatric Minimal Sedation

§ 1043.9. Definitions.

For purposes of this Article, the terms set forth below shall be defined as follows:

(a) "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 described in subdivision (a)(2) of Section 1647.31 of the Code.

(b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility ~~which~~ that is accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

(c) "Pediatric patient" means a patient under 13 years of age.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.31, Business and Professions Code.

§ 1043.9.1. Requirements; Standards.

(a) A licensed dentist who desires to administer or order the administration of pediatric minimal sedation on an outpatient basis is not required to apply to the Board for a pediatric minimal sedation permit if they possess another sedation permit from the Board.

(b) For 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.

(c) The office in which the pediatric minimal sedation is administered shall meet the facilities and equipment standards set forth in Section 1043.9.2.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.31 and 1647.32, Business and Professions Code.

§ 1043.9.2. Facility and Equipment Standards.

A facility in which minimal sedation is administered to pediatric patients pursuant to this article shall meet the standards set forth herein. All equipment should be maintained, tested and inspected according to the manufacturers' specifications. In an office where minimal sedation services are to be provided to pediatric patients, the required equipment, medication and resuscitative capabilities shall be appropriately sized for use on a pediatric population.

(a) Facility and Equipment. A facility shall possess:

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

(6) Inhalation 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.

(b) An 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. Emergency drugs of the following types shall be available:

(1) Epinephrine,

(2) Bronchodilator,

(3) Appropriate drug antagonists,

(4) Antihistaminic,

(5) Anticholinergic,

(6) Anticonvulsant,

(7) Oxygen, and,

(8) Dextrose or other antihypoglycemic.

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

(1) Oral airways capable of accommodating pediatric patients of all sizes.

(2) A sphygmomanometer with cuffs of appropriate size for pediatric patients of all sizes.

(3) A precordial/pretracheal stethoscope.

(4) A pulse oximeter.

(d) A facility must maintain the following records:

(1) 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 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.

(2) 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.

(3) Documentation that all emergency equipment is checked to determine operability and safety for the patient consistent with the manufacturer's recommendation.

(4) 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.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.30 and 1647.32, Business and Professions Code.

Article 5.5. Oral Conscious Sedation

§ 1044. Definitions.

For purposes of this Article and of Articles ~~2.85 and~~ 2.86, of Chapter 4, of Division 2 of the Code, the terms set forth below shall be defined as follows:

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

(b) A patient under oral conscious sedation shall be considered "sedated" for that period of time beginning with the administration of oral conscious sedation and continuing until that time when the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient.

(c) "Age-appropriate" means ~~under 13 years of age for the oral conscious sedation certificate for minor patients and~~ 13 years or older for the oral conscious sedation certificate for adult patients.

(d) For the purposes of adult oral conscious sedation, administering a drug to a patient in a dose that exceeds the maximum recommended dose as established and listed by the United States Food and Drug Administration (FDA) on the drug's FDA-approved professional labeling insert or packaging information shall be considered to exceed the single maximum dose that can be prescribed for home use.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections ~~1647.10 and~~ 1647.18, Business and Professions Code.

§ 1044.1. Requirements; Standards.

An applicant for an oral conscious sedation certificate shall submit to the Board ~~either~~ ~~an "Application for Oral Conscious Sedation for Minors Certificate" OCS-1 (Rev. 01/05)~~ ~~or~~ an completed ~~"Application for Adult Oral Conscious Sedation Certificate" OCS-3 (Rev. 03/07)~~"Application for Use of Oral Conscious Sedation on Adult Patients" Form OCS-C (New 05/2021), which is hereby incorporated by reference, ~~and shall be~~ accompanied by the applicable fee as set by Section 1021. A dentist is not required to possess an oral conscious sedation certificate if the oral conscious sedation administered to his or her patient is directly administered and monitored by a dentist who possesses a general anesthesia permit, a ~~conscious~~moderate sedation permit~~, or an oral conscious sedation certificate for a minor patient~~ or is administered by a licensed physician and surgeon who possesses a general anesthesia permit. ~~A dentist who only possesses an adult oral conscious sedation certificate may not provide oral conscious sedation to a minor patient.~~ Notwithstanding the above, the office in which the oral conscious sedation is administered shall meet the facilities and equipment standards set forth in Section 1044.5.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections ~~1647.10, 1647.11,~~ 1647.18 and 1647.19, Business and Professions Code.

§ 1044.2. Board Approved Programs.

(a) For purposes of ~~Section 1647.12(b) and~~ Section 1647.20(b) of the Code, a post-doctoral program in periodontics, a general practice residency or advanced education in a general dentistry post-doctoral program accredited by the Commission on Dental Accreditation that meets the didactic and clinical requirements of Section 1044.3 shall be deemed to be approved by the B~~b~~oard. A dentist must submit a copy of his or her certificate of completion from a B~~b~~oard approved educational program as defined in Section 1044.3 or diploma from a recognized dental residency or post-doctoral program as defined in this section.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections ~~1647.10, 1647.12,~~ 1617.18 and 1647.20, Business and Professions Code.

§ 1044.3. Board Approved Education.

(a) The goal of an instructional program in oral medications and sedation is to provide the educational opportunity for dentists to receive training in the techniques and skills required to safely and effectively administer oral pharmacologic agents, alone or in combination with nitrous oxide-oxygen inhalation, for the purpose of obtaining conscious sedation in the ~~minor or~~ adult dental patient.

(b) The educational program shall be approved by the Bboard and shall consist of satisfactory completion of at least 25 hours of instruction including a clinical componentutilizing at least one age-appropriate patient. ~~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.~~ The program shall include but not be limited to, the following areas:

(1) Historical, philosophical, and legal aspects of age-appropriate oral conscious sedation of dental patients, including the ~~Business and Professions~~ Code.
(2) Indications and contraindications for the utilization of age-appropriate oral conscious sedation in dental patients.
(3) Patient evaluation and selection through a review of the medical history, physical assessment, and medical consultation.
(4) Definitions and characteristics for levels of sedation achieved with oral sedative agents, with special emphasis on the distinctions between ~~conscious~~moderate sedation, deep sedation, and general anesthesia as recognized by such organizations as the American Dental Association ~~and the American Academy of Pediatric Dentistry~~ and the board
(5) Review of respiratory and circulatory physiology and related anatomy, with special emphasis on, and clinical experience in, establishing and maintaining an age-appropriate patent airway in the patient.
(6) Pharmacology of agents used in contemporary oral conscious sedation techniques, including drug interactions, incompatibilities and side effects and adverse reactions.

(7) Indications, contraindications, and technique considerations in the use of different contemporary age-appropriate oral conscious sedation modalities for dental patients.

(8) Patient monitoring during all stages of the procedure by clinical observation and appropriate mechanical devices for responsiveness, airway patency, and recording of vital signs.

(9) Importance of and techniques for maintaining proper documentation of the procedure, including aspects of informed consent, pre- and post-operative instructions, dietary considerations, preoperative health evaluation, rationale for the procedure, baseline and intermittent vital signs, a detailed record of all oral and inhalation drugs administered, the patient response to the drugs, and recovery and discharge criteria.

(10) Prevention, recognition and management of complications and life-threatening situations that may arise during age-appropriate oral conscious sedation of the dental patient, including the principles of advanced life support.

(c) A provider of a course in oral medications and sedation intending to meet the requirements of this section shall submit to the board an application, on form OCS-6 (rev. 07/07), “Application for Course Approval for Oral Conscious Sedation,”

incorporated herein by reference. The board may approve or deny approval of any such course. Approval shall be granted after an evaluation of all components of the course has been performed and such evaluation indicates that the course meets therequirements of this section.

(d) Approval by the board of a course in oral medications and sedation shall remain in effect for a period of twenty-four months, unless withdrawn sooner, after which a new application for approval must be submitted to the board.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections ~~1647.10, 1647.12 and~~ 1647.20, Business and Professions Code.

§ 1044.4. Documentation of 10 Cases.~~[Repealed]~~

(a) For the purposes of Section 1647.20(d), an applicant for an oral conscious sedation certificate for adult patients who has been using oral conscious sedation in connection with the treatment of adult patients shall submit the following documentation for each of the 10 cases of oral conscious sedation on form OCS-4 (Rev 03/07) “Documentation of Oral Conscious Sedation Cases,” incorporated herein by reference.

(1) Patient's sex, age, and weight.

(2) Date of oral conscious sedation procedure.

(3) Type of dental procedure performed and duration of sedation.

(4) A description of the method, amount, and specific oral conscious sedation agent administered.

(5) A statement on how the patient was monitored and by whom.

(6) Patient's condition at discharge.

(b) Applicants shall also provide documentation or patient records for each oral conscious sedation case, including preoperative evaluation, medical history, monitoring of vital signs throughout the procedure, and condition at discharge for each patient.

(c) Applicants shall submit legible copies of the above required information with patient identifying information redacted.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.10, 1647.12, 1647.20 and 1647.22, Business and Professions Code.

§ 1044.5. Facility and Equipment Standards.

All equipment shall be maintained, tested and inspected according to the manufacturers’ specifications. A facility in which oral conscious sedation is administered

to patients pursuant to this article shall also meet the standards set forth below.

(a) Facility and Equipment.

(1) 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.

(2) 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.

(3) A lighting system which 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 which may be underway at the time of a general power failure.

(4) 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.

(5) 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 age-appropriate and capable of accommodating the patients being seen at the permit-holder's office.

(6) Inhalation sedation equipment, if used in conjunction with oral sedation, must have 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 have a fail-safe system. The equipment must be maintained and checked for accuracy at least annually.

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

(7) Age-appropriate oral airways capable of accommodating patients of all sizes.

(8) An age-appropriate sphygmomanometer with cuffs of appropriate size for patients of all sizes.

(9) A precordial/pretracheal stethoscope.

(10) A pulse oximeter.

(c)The following records shall be maintained:

(11) An 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 ~~minor~~ 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 ~~parent or legal guardian of the patient~~.

(12) Oral conscious sedation records shall include 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 recording of oxygen saturation, heartand 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.

(d) An emergency cart or kit shall be available and readily accessible and shall include the necessary and appropriate drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious patient and provide continuous support while the patient is transported to a medical facility. There must be documentation showing that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis. Emergency drugs of the following types shall be available:

(13) Epinephrine

(14) Bronchodilator

(15) Appropriate drug antagonists

(16) Antihistaminic

(17) Anticholinergic

(18) Anticonvulsant

(19) Oxygen

(20) Dextrose or other antihypoglycemic

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections ~~1647.10, 1647.16,~~ 1647.22 and 1647.24, Business and Professions Code.

Chapter 3. Dental Auxiliaries

Article 2. Educational Programs

§ 1070.8. Approval of Dental Sedation Assistant Permit Courses.

In addition to the requirements of Sections 1070 and 1070.1, the following criteria shall be met by a dental sedation assistant permit course to secure and maintain approval by the Board. As used in this ~~S~~section, the following definitions apply: “IV” means intravenous, “AED” means automated external defibrillator, “CO2” means carbon dioxide, and “ECG” and “EKG” both mean electrocardiogram.

(a)(1) The course director, designated faculty member, or instructional staff member may, in lieu of a license issued by the Board, possess a valid, active, and current license issued in California as a physician and surgeon.

(2) The course director, designated faculty member, or instructional staff member responsible for clinical evaluation shall have completed a two-hour methodology course in clinical evaluation prior to conducting clinical evaluations of students.

(3) Clinical instruction shall be given under direct supervision of the course director, designated faculty member, or instructional staff member who shall be the holder of a valid, active, and current general anesthesia or ~~conscious~~ moderate sedation permit issued by the Board. Evaluation of the condition of a sedated patient shall remain the responsibility of the director, designated faculty member, or instructional staff member authorized to administer ~~conscious~~ moderate sedation, deep sedation, or general anesthesia, who shall be at the patient's chairside while ~~conscious~~ moderate sedation, deep sedation, or general anesthesia is being administered.

(b) The course shall be of a sufficient duration for the student to develop minimum competence in all of the duties that dental sedation assistant permitholders are authorized to perform, but in no event less than 110 hours, including at least 40 hours of didactic instruction, at least 32 hours of combined laboratory and preclinical instruction, and at least 38 hours of clinical instruction. Clinical instruction shall require completion of all of the tasks described in ~~subdivisions~~subsections (j), (k), (l), (m), and (n) ~~of this Section~~ during no less than twenty (20) supervised cases utilizing ~~conscious~~ moderate sedation, deep sedation, or general anesthesia.

(c) The following are minimum requirements for equipment and armamentaria:

(1) One pulse oximeter for each six students; one AED or AED trainer; one capnograph or teaching device for monitoring of end tidal CO2; blood pressure cuff and stethoscope for each six students; one pretracheal stethoscope for each six students; one electrocardiogram machine, one automatic blood pressure/pulse measuring system/machine, and one oxygen delivery system including oxygen tank;

one IV start kit for each student; one venous access device kit for each student; IV equipment and supplies for IV infusions including hanging device infusion containers and tubing for each six students; one sharps container for each six students; packaged syringes, needles, needleless devices, practice fluid ampules and vials for each student; stopwatch or timer with second hand for each six students; one heart/lung sounds mannequin or teaching device; tonsillar or pharyngeal suction tip, endotracheal tube forceps, endotracheal tube and appropriate connectors, suction equipment for aspiration of oral and pharyngeal cavities, and laryngoscope in the ratio of at least one for each six students; any other monitoring or emergency equipment required by ~~Cal. Code Regs., Title 16,~~ Section 1043 for the administration of general anesthesia, deep sedation, or ~~conscious~~ moderate sedation; and a selection of instruments and supplemental armamentaria for all of the procedures that dental sedation assistant permitholders are authorized to perform according to ~~Business and Professions Code~~ Section 1750.5 of the Code.

(2) Each operatory used for preclinical or clinical training shall contain either a surgery table or a power-operated chair for treating patients in a supine position, an irrigation system or sterile water delivery system as they pertain to the specific practice, and all other equipment and armamentarium required to instruct in the duties that dental sedation assistant permitholders are authorized to perform according to ~~Business and Professions Code~~ Section 1750.5 of the Code.

(3) All students, faculty, and staff involved in the direct provision of patient care shall be certified in basic life support procedures, including the use of an automatic electronic defibrillator.

(d) Areas of instruction shall include, at a minimum, the instruction specified in ~~subdivisions~~subsections (e) to (n), inclusive, as they relate to the duties that dental sedation assistant permitholders are authorized to perform.

(e) General didactic instruction shall contain:

(1) Patient evaluation and selection factors through review of medical history, physical assessment, and medical consultation.

(2) Characteristics of anatomy and physiology of the circulatory, cardiovascular, and respiratory systems, and the central and peripheral nervous system.

(3) Characteristics of anxiety management related to the surgical patient, relatives, and escorts, and characteristics of anxiety and pain reduction techniques.

(4) Overview of the classification of drugs used by patients for cardiac disease, respiratory disease, hypertension, diabetes, neurological disorders, and infectious diseases.

(5) Overview of techniques and specific drug groups utilized for sedation and general anesthesia.

(6) Definitions and characteristics of levels of sedation achieved with general anesthesia and sedative agents, including the distinctions between ~~conscious~~ moderate sedation, deep sedation, and general anesthesia.

(7) Overview of patient monitoring during ~~conscious~~ moderate sedation, deep sedation, and general anesthesia.

(8) Prevention, recognition, and management of complications.

(9) Obtaining informed consent.

(f) With respect to medical emergencies, didactic instruction shall contain:

(1) An overview of medical emergencies, including, but not limited to, airway obstruction, bronchospasm or asthma, laryngospasm, allergic reactions, syncope, cardiac arrest, cardiac dysrhythmia, seizure disorders, hyperglycemia and hypoglycemia, drug overdose, hyperventilation, acute coronary syndrome including angina and myocardial infarction, hypertension, hypotension, stroke, aspiration of vomitus, and congestive heart failure.

(2) Laboratory instruction shall include the simulation and response to at least the following medical emergencies: airway obstruction, bronchospasm, emesis and aspiration of foreign material under anesthesia, angina pectoris, myocardial infarction, hypotension, hypertension, cardiac arrest, allergic reaction, convulsions, hypoglycemia, syncope, and respiratory depression. Both training mannequins and other students or staff may be used for simulation. The student shall demonstrate proficiency in all simulated emergencies during training and shall then be eligible to complete a practical examination on this ~~S~~section.

(g) With respect to sedation and the pediatric patient, didactic instruction shall contain the following:

(1) Psychological considerations.

(2) Patient evaluation and selection factors through review of medical history, physical assessment, and medical consultation.

(3) Definitions and characteristics of levels of sedation achieved with general anesthesia and sedative agents, with special emphasis on the distinctions between ~~conscious~~ moderate sedation, deep sedation, and general anesthesia.

(4) Review of respiratory and circulatory physiology and related anatomy, with special emphasis on establishing and maintaining a patient airway.

(5) Overview of pharmacology agents used in contemporary sedation and general anesthesia.

(6) Patient monitoring.

(7) Obtaining informed consent.

(8) Prevention, recognition, and management of complications, including principles of basic life support and resuscitation of pediatric patients.

(h) With respect to physically, mentally, and neurologically compromised patients, didactic instruction shall contain the following: an overview of characteristics of Alzheimer's disease, autism, cerebral palsy, Down's syndrome, mental retardation, multiple sclerosis, muscular dystrophy, Parkinson's disease, schizophrenia, and stroke.

(i) With respect to health history and patient assessment, didactic instruction shall include, at a minimum, the recording of the following:

(1) Age, sex, weight, physical status as defined by the American Society of Anesthesiologists Physical Status Classification System, medication use, general health, any known or suspected medically compromising conditions, rationale for anesthesia or sedation of the patient, visual examination of the airway, and auscultation of the heart and lungs as medically required.

(2) General anesthesia, deep sedation, or ~~conscious~~ moderate sedation records that contain a time-oriented record with preoperative, multiple intraoperative, and postoperative pulse oximetry and blood pressure and pulse readings, frequency and dose of drug administration, length of procedure, complications of anesthesia or sedation, and a statement of the patient's condition at time of discharge.

(j) With respect to monitoring heart sounds with pretracheal/precordial stethoscope and EKG and use of AED:

(1) Didactic instruction shall contain the following:
(A) Characteristics of pretracheal/precordial stethoscope.
(B) Review of anatomy and physiology of circulatory system: heart, blood vessels, and cardiac cycle as it relates to EKG.
(C) Characteristics of rhythm interpretation and waveform analysis basics.
(D) Characteristics of manual intermittent and automatic blood pressure and pulse assessment.
(E) Characteristics and use of an AED.
(F) Procedure for using a pretracheal/precordial stethoscope for monitoring of heart sounds.
(G) Procedure for use and monitoring of the heart with an EKG machine, including electrode placement, and the adjustment of such equipment.

(H) Procedure for using manual and automatic blood pressure/pulse/respiration measuring system.

(2) Preclinical instruction: Utilizing another student or staff person, the student shall demonstrate proficiency in each of the following tasks during training and shall then be eligible to complete an examination on this ~~S~~section.

(A) Assessment of blood pressure and pulse both manually and utilizing an automatic system.

(B) Placement and assessment of an EKG. Instruction shall include the adjustment of such equipment.

(C) Monitoring and assessment of heart sounds with a pretracheal/precordial stethoscope.

(D) Use of an AED or AED trainer.

(3) Clinical instruction: Utilizing patients, the student shall demonstrate proficiency in each of the following tasks, under supervision of faculty or instructional staff as described in ~~S~~section 1070.8(a)(3), and shall then be eligible to complete an examination on this ~~S~~section.

(A) Assessment of blood pressure and pulse both manually and utilizing an automatic system.

(B) Placement and assessment of an EKG. Instruction shall include the adjustment of such equipment.

(C) Monitoring and assessment of heart sounds with a pretracheal/precordial stethoscope.

(k) With respect to monitoring lung/respiratory sounds with pretracheal/precordial stethoscope and monitoring oxygen saturation end tidal CO2 with pulse oximeter and capnograph:

(1) Didactic instruction shall contain the following:

(A) Characteristics of pretracheal/precordial stethoscope, pulse oximeter and capnograph for respiration monitoring.

(B) Review of anatomy and physiology of respiratory system to include the nose, mouth, pharynx, epiglottis, larynx, trachea, bronchi, bronchioles, and alveolus.

(C) Characteristics of respiratory monitoring/lung sounds: mechanism of respiration, composition of respiratory gases, oxygen saturation.

(D) Characteristics of manual and automatic respiration assessment.

(E) Procedure for using a pretracheal/precordial stethoscope for respiration monitoring.

(F) Procedure for using and maintaining pulse oximeter for monitoring oxygen saturation.

(G) Procedure for use and maintenance of capnograph.

(H) Characteristics for monitoring blood and skin color and other related factors.

(I) Procedures and use of an oxygen delivery system.

(J) Characteristics of airway management to include armamentaria and use.

(2) Preclinical instruction: Utilizing another student or staff person, the student shall demonstrate proficiency in each of the following tasks during training and shall then be eligible to complete an examination on this ~~S~~section.

(A) Assessment of respiration rates.

(B) Monitoring and assessment of lung sounds and ventilation with a pretracheal/precordial stethoscope.

(C) Monitoring oxygen saturation with a pulse oximeter.

(D) Use of an oxygen delivery system.

(3) Clinical instruction: Utilizing patients, the student shall demonstrate proficiency in each of the following tasks, under supervision by faculty or instructional staff as described in Section 1070.8(a)(3), and shall then be eligible to complete an examination on this ~~S~~section.

(A) Assessment of respiration rates.

(B) Monitoring and assessment of lung sounds and ventilation with a pretracheal/precordial stethoscope.

(C) Monitoring oxygen saturation with a pulse oximeter.

(D) Use of an oxygen delivery system.

(l) With respect to drug identification and draw:

(1) Didactic instruction shall contain:

(A) Characteristics of syringes and needles: use, types, gauges, lengths, and components.

(B) Characteristics of drug, medication, and fluid storage units: use, type, components, identification of label including generic and brand names, strength, potential adverse reactions, expiration date, and contraindications.

(C) Characteristics of drug draw: armamentaria, label verification, ampule and vial preparation, and drug withdrawal techniques.

(2) Laboratory instruction: The student shall demonstrate proficiency in the withdrawal of fluids from a vial or ampule in the amount specified by faculty or instructional staff and shall then be eligible to complete a practical examination.

(3) Clinical instruction: The student shall demonstrate proficiency in the evaluation of vial or container labels for identification of content, dosage, and strength and in the withdrawal of fluids from a vial or ampule in the amount specified by faculty or instructional staff as described in Section 1070.8(a)(3), and shall then be eligible to complete an examination on this ~~S~~section.

(m) With respect to adding drugs, medications, and fluids to IV lines:

(1) Didactic instruction shall contain:

(A) Characteristics of adding drugs, medications, and fluids to IV lines in the presence of a licensed dentist.

(B) Armamentaria.

(C) Procedures for adding drugs, medications, and fluids, including dosage and frequency.
(D) Procedures for adding drugs, medications, and fluids by IV bolus.
(E) Characteristics of patient observation for signs and symptoms of drug response.

(2) Laboratory instruction: The student shall demonstrate proficiency in adding fluids to an existing IV line on a venipuncture training arm or in a simulated environment, and shall then be eligible to complete a practical examination on this ~~S~~section.

(3) Clinical instruction: The student shall demonstrate proficiency in adding fluids to existing IV lines in the presence of course faculty or instructional staff as described in Section 1070.8(a)(3), and shall then be eligible to complete an examination on this ~~S~~section.

(n) With respect to the removal of IV lines:

(1) Didactic instruction shall include overview and procedures for the removal of an IV line.

(2) Laboratory instruction: The student shall demonstrate proficiency on a venipuncture training arm or in a simulated environment for IV removal, and shall then be eligible for a practical examination.

(3) Clinical instruction: The student shall demonstrate proficiency in removing IV lines in the presence of course faculty or instructional staff as described in Section 1070.8(a)(3), and shall then be eligible to complete an examination on this ~~S~~section.

(o) Each student shall pass a written examination that reflects the curriculum content, which may be administered at intervals throughout the course as determined by the course director.

(p) To maintain approval, programs approved prior to the effective date of these regulations shall submit to the Board a completed “Notice of Compliance with New Requirements for Dental Sedation Assistant Permit Courses (New 10/10)”, hereby incorporated by reference, within ninety (90) days of the effective date of these regulations.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1750.4, 1750.5 and 1752.4, Business and Professions Code.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DENTAL BOARD OF CALIFORNIA
2005 Evergreen St., Suite 1550, Sacramento, CA 95815
P (916) 263-2300 | F (916) 263-2140 | www.dbc.ca.gov

APPLICATION FOR GENERAL ANESTHESIA PERMIT

FEES Application Fee: $524.00 (Must be enclosed with application) **APPLICATION FEES ARE NON-REFUNDABLE**	*For Office Use Only* Rec # _____ Fee Pd _____ Date Cashiered _____ Entity# _____ File # _____	*For Office Use Only* Date Received

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

(PLEASE PRINT CLEARLY OR TYPE)

1. SSN/ITIN:	2. BIRTH DATE (MM/DD/YYYY):
3. LEGAL NAME: LAST FIRST MIDDLE	
4. MAILING ADDRESS [ADDRESS OF RECORD – ADDRESS MAY BE A P.O. BOX]:	
5. PRIMARY PRACTICE LOCATION (PHYSICAL ADDRESS):	
6. EMAIL ADDRESS [OPTIONAL]:	
7. TELEPHONE NUMBER:	
8. FAX NUMBER [OPTIONAL]	
9. DENTAL OR MEDICAL LICENSE NUMBER:	

10. **APPLICANT RESIDENCY TRAINING**.

A. **FOR DENTAL LICENSEES**:

HAVE YOU COMPLETED A RESIDENCY PROGRAM IN GENERAL ANESTHESIA OR A RESIDENCY PROGRAM IN ORAL OR MAXILLOFACIAL SURGERY ACCREDITED BY THE AMERICAN DENTAL ASSOCIATION'S COMMISSION ON DENTAL ACCREDITATION?

YES ☐

NO ☐

PLEASE SUBMIT WITH THIS APPLICATION A CERTIFICATE OF COMPLETION OR OTHER DOCUMENTARY EVIDENCE SHOWING COMPLETION OF ONE OF THE FOLLOWING:

(1) A RESIDENCY PROGRAM IN GENERAL ANESTHESIA ACCREDITED BY THE AMERICAN DENTAL ASSOCIATION COMMISSION ON DENTAL ACCREDITATION; OR

(2) A RESIDENCY PROGRAM IN ORAL AND MAXILLOFACIAL SURGERY ACCREDITED BY THE AMERICAN DENTAL ASSOCIATION'S COMMISSION ON DENTAL ACCREDITATION.

B. **FOR PHYSICIAN AND SURGEON LICENSEES**:

HAVE YOU COMPLETED A POSTGRADUATE RESIDENCY TRAINING PROGRAM IN ANESTHESIOLOGY THAT IS RECOGNIZED BY THE AMERICAN COUNCIL ON GRADUATE MEDICAL EDUCATION?

YES ☐

NO ☐

IF YOU ANSWERED "YES" TO THIS QUESTION, YOU ARE ALSO REQUIRED TO SUBMIT A COPY OF THIS COMPLETED APPLICATION TO THE MEDICAL BOARD OF CALIFORNIA SO THAT THE DENTAL BOARD OF CALIFORNIA MAY VERIFY WITH THAT AGENCY THAT YOU HAVE COMPLETED THE REQUIRED TRAINING (BUSINESS AND PROFESSIONS CODE SECTION 2079).

11. IN ADDITION TO A GENERAL ANESTHESIA PERMIT, ARE YOU APPLYING FOR A PEDIATRIC ENDORSEMENT TO ADMINISTER DEEP SEDATION AND GENERAL ANESTHESIA TO A PATIENT UNDER 7?

YES ☐

NO ☐

IF YOU ANSWERED "YES" TO THIS QUESTION, YOU MUST COMPLETE A SEPARATE APPLICATION FOR A PEDIATRIC ENDORSEMENT AND MEET THE REQUIREMENTS IN SECTION 1043.8.1 OF TITLE 16 OF THE CALIFORNIA CODE OF REGULATIONS. YOU MAY APPLY FOR A PEDIATRIC ENDORSEMENT SIMULTANEOUSLY BY SUBMITTING BOTH APPLICATIONS AT THE SAME TIME YOU MAY ALSO APPLY SEPARATELY FOR A PEDIATRIC ENDORSEMENT AT A LATER DATE BY COMPLETING THE APPLICATION AND MEETING THE REQUIREMENTS IN SECTION 1043.8.1.

NOTICE: PLEASE SEE ATTACHED MONITORING REQUIREMENTS IN BUSINESS AND PROFESSIONS CODE, SECTION 1646.1, 1646.2, AND CALIFORNIA CODE OF REGULATIONS, TITLE 16, SECTION 1043.8.1.

PLEASE CHECK THIS BOX IF YOU WOULD LIKE THE PEDIATRIC ENDORSEMENT APPLICATION PROCESSED ALONG WITH THIS APPLICATION: ☐

12. ARE YOU SERVING IN, OR HAVE YOU PREVIOUSLY SERVED IN, THE U.S. MILITARY?

YES ☐

NO ☐

13. ARE YOU REQUESTING EXPEDITING OF THIS APPLICATION FOR HONORABLYDISCHARGED MEMBERS OF THE U.S. ARMED FORCES? *MILITARY HONORABLE DISCHARGE REQUIREMENTS* NOTE: PLEASE SCAN AND ATTACH A COPY OF THE FOLLOWING DOCUMENTATION ON THE ATTACHMENTS PAGE OF THIS APPLICATION: CERTIFICATE OF RELEASE OR DISCHARGE FROM ACTIVE DUTY (DD-214) OR OTHER DOCUMENTARY EVIDENCE SHOWING DATE AND TYPE OF DISCHARGE TO RECEIVE EXPEDITED REVIEW.	YES ☐ NO ☐
14. DO YOU ALREADY HOLD A VALID LICENSE, OR COMPARABLE AUTHORITY, TO PRACTICE DENTISTRY IN ANOTHER U.S. STATE OR TERRITORY, AND YOUR SPOUSE OR DOMESTIC PARTNER IS AN ACTIVE DUTY MEMBER OF THE ARMED FORCES OF THE UNITED STATES AND WAS ASSIGNED TO A DUTY STATION IN CALIFORNIA UNDER OFFICIAL ORDERS? IF YES, YOUR APPLICATION WILL RECEIVE AN EXPEDITED REVIEW. *MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENTS* NOTE: IF YOU MEET THE MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENT PLEASE SCAN AND ATTACH THE FOLLOWING DOCUMENTATION ON THE ATTACHMENTS PAGE OF THIS APPLICATION: • 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 • A COPY OF YOUR CURRENT DENTAL LICENSE IN ANOTHER STATE, DISTRICT, OR TERRITORY OF THE UNITED STATES. • A COPY OF THE MILITARY ORDERS ESTABLISHING YOUR SPOUSE OR PARTNER'S DUTY STATION IN CALIFORNIA	YES ☐ NO ☐
15. DO ANY OF THE FOLLOWING STATEMENTS APPLY TO YOU: • YOU WERE ADMITTED TO THE UNITED STATES AS A REFUGEE PURSUANT TO SECTION 1157 OF TITLE 8 OF THE UNITED STATES CODE; OR • YOU WERE 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, • YOU HAVE A SPECIAL IMMIGRANT VISA AND WERE 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]. IF YOU SELECTED YES, YOU MUST ATTACH EVIDENCE OF YOUR STATUS AS A REFUGEE, ASYLEE, OR SPECIAL IMMIGRANT VISA HOLDER AS PROVIDED BELOW. FAILURE TO DO SO MAY RESULT IN APPLICATION PROCESSING. "EVIDENCE" SHALL INCLUDE: • 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" • 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 THEAPPLICANT QUALIFIES FOR EXPEDITED LICENSURE PER BUSINESS AND PROFESSIONS CODE SECTION 135.4.	YES ☐ NO ☐

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 TO PEDIATRIC PATIENTS, THE REQUIRED EQUIPMENT, MEDICATION AND RESUSCITATIVE CAPABILITIES SHALL BE APPROPRIATELY SIZED FOR USE ON A PEDIATRIC POPULATION.	
16. DOES THE FACILITY HAVE AN OPERATING THEATER LARGE ENOUGH TO ADEQUATELY ACCOMMODATE THE PATIENT ON A TABLE OR IN AN OPERATING CHAIR AND PERMIT AN OPERATING TEAMCONSISTING OF AT LEAST THREE INDIVIDUALS TO FREELY MOVE ABOUT THE PATIENT?	YES ☐ NO ☐
17. DOES THE FACILITY HAVE 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 PROVIDE A FIRM PLATFORM FOR THE MANAGEMENT OF CARDIOPULMONARY RESUSCITATION?	YES ☐ NO ☐
18. DOES 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?	YES ☐ NO ☐
19. DOES THE FACILITY HAVE SUCTION EQUIPMENT THAT PERMITS ASPIRATION OF THE ORAL AND PHARYNGEAL CAVITIES AND A BACKUP SUCTION DEVICE THAT CAN OPERATE AT THE TIME OF GENERAL POWER FAILURE?	YES ☐ NO ☐
20. DOES THE FACILITY HAVE 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?	YES ☐ NO ☐
21. DOES THE FACILITY HAVE A RECOVERY AREA THAT HAS AVAILABLE OXYGEN, ADEQUATE LIGHTING, SUCTION AND ELECTRICAL OUTLETS? THE RECOVERY AREA CAN BE THE OPERATING THEATER.	YES ☐ NO ☐
22. DOES THE FACILITY HAVE ANCILLARY EQUIPMENT MAINTAINED IN GOOD OPERATING CONDITION, WHICH MUST INCLUDE ALL OF THE FOLLOWING: (a) LARYNGOSCOPE COMPLETE WITH ADEQUATE SELECTION OF BLADES AND SPARE BATTERIES AND BULB. (b) ENDOTRACHEAL TUBES AND APPROPRIATE CONNECTORS. (c) EMERGENCY AIRWAY EQUIPMENT (ORAL AIRWAYS, LARYNGEAL MASK AIRWAYS OR COMBITUBES, CRICOTHYROTOMY DEVICE). (d) TONSILLAR OR PHARYNGEAL TYPE SUCTION TIPS ADAPTABLE TO ALL OFFICE OUTLETS. (e) ENDOTRACHEAL TUBE FORCEPS. (f) SPHYGMOMANOMETER AND STETHOSCOPE. (g) ELECTROCARDIOSCOPE AND DEFIBRILLATOR. (h) ADEQUATE EQUIPMENT FOR THE ESTABLISHMENT OF AN INTRAVENOUS INFUSION. (i) PRECORDIAL/PRETRACHEAL STETHOSCOPE. (j) PULSE OXIMETER (k) CAPNOGRAPH AND TEMPERATURE DEVICE. PATIENTS RECEIVING DEEP SEDATION, GENERAL ANESTHESIA, OR MODERATE SEDATION SHALL HAVE VENTILATION CONTINUOUSLY MONITORED DURING THE PROCEDURE BY TWO OF THE FOLLOWING METHODS: (i) AUSCULTATION OF BREATH SOUNDS USING A PRECORDIAL STETHOSCOPE. (ii) MONITORING FOR THE PRESENCE OF EXHALED CARBON DIOXIDE WITH CAPNOGRAPHY.	YES ☐ NO ☐

RECORDS - DO YOU MAINTAIN THE FOLLOWING RECORDS?	
23. ADEQUATE MEDICAL HISTORY AND PHYSICAL EVALUATION RECORDS UPDATED PRIOR TO EACH ADMINISTRATION OF DEEP SEDATION AND GENERAL ANESTHESIA. SUCH RECORDS SHALL INCLUDE BUT ARE NOT LIMITED TO THE RECORDING OF THE AGE, SEX, WEIGHT, PHYSICAL STATUS (AMERICAN SOCIETY OF ANESTHESIOLOGISTS CLASSIFICATION), MEDICATION USE, ANY KNOWN OR SUSPECTED MEDICALLY COMPROMISING CONDITIONS, RATIONALE FOR SEDATION OF THE PATIENT, AND AN EVALUATION OF THE AIRWAY, AND AUSCULTATION OF THE HEART AND LUNGS ~~AS MEDICALLY REQUIRED~~.	YES ☐ NO ☐
24. GENERAL ANESTHESIA OR DEEP SEDATION RECORDS, WHICH SHALL 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.	YES ☐ NO ☐
25. RECORDS INCLUDING 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, WHETHER THE PERSON SUPERVISING THE SEDATION PERFORMED ONE OR MORE OF THE PROCEDURES.	YES ☐ NO ☐
26. WRITTEN INFORMED CONSENT OF THE PATIENT, OR, AS APPROPRIATE, PATIENT'S CONSERVATOR, OR THE INFORMED CONSENT OF A PERSON AUTHORIZED TO GIVE SUCH CONSENT FOR THE PATIENT, OR IF THE PATIENT IS A MINOR, ~~OR~~ HIS OR HER PARENT OR GUARDIAN, PURSUANT TO BUSINESS AND PROFESSIONS CODE SECTION 1682(e).	YES ☐ NO ☐
27. **DRUGS** - DO YOU MAINTAIN EMERGENCY DRUGS OF THE FOLLOWING TYPES AT ALL TIMES IN CONNECTION WITH THE ADMINISTRATION OF DEEP SEDATION OR GENERAL ANESTHESIA? • EPINEPHRINE (EPI) • VASOPRESSOR (OTHER THAN EPI) • BRONCHODILATOR • MUSCLE RELAXANT • INTRAVENOUS MEDICATION FOR TREATMENT OF CARDIOPULMONARY ARREST • APPROPRIATE DRUGS ANTAGONIST • ANTIHISTAMINIC • ANTICHOLINGERGIC • ANTIARRHYTHMIC • CORONARY ARTERY VASODILATOR • ANTIHYPERTENSIVE • ANTICONVULSANT • OXYGEN • 50% DEXTROSE OR OTHER ANTIHYPOGLYCEMIC	YES ☐ NO ☐
28. **EMERGENCIES** - ARE YOU COMPETENT TO TREAT ALL OF THE FOLLOWING EMERGENCIES? • AIRWAY OBSTRUCTION • BRONCHOSPASM • EMESIS AND ASPIRATION OF FOREIGN MATERIAL UNDER ANESTHESIA • ANGINA PECTORIS • MYOCARDIAL INFARCTION • HYPOTENSION • HYPERTENSION • CARDIAC ARREST • ALLERGIC REACTION • CONVULSIONS • HYPOGLYCEMIA • SYNCOPE • RESPIRATORY DEPRESSION	YES ☐ NO ☐
29. **STAFF**- ARE DENTAL OFFICE PERSONNEL DIRECTLY INVOLVED WITH THE CARE OF PATIENTS UNDERGOING DEEP SEDATION OR GENERAL ANESTHESIA CERTIFIED IN BASIC CARDIAC LIFE SUPPORT (CPR)?	YES ☐ NO ☐

30. PROVIDE THE ADDRESSES OF ALL LOCATIONS OF PRACTICE WHERE YOU ADMINISTER OR ORDER THE ADMINISTRATION OF DEEP SEDATION OR GENERAL ANESTHESIA IF YOU ARE A PHYSICIAN AND SURGEON APPLYING FOR THIS PERMIT, PROVIDE THE NAMES OF ANY HOSPITALS WHERE YOU HAVE MEMBERSHIP ON THE MEDICAL STAFF.

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_____

_____

IF NECESSARY, CONTINUE ON THE BACK OF THIS PAGE.

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing information, including any attached statements, is true and correct.

_____

Date Signature of Applicant

INFORMATION COLLECTION AND ACCESS Except for the email address and fax number, the information requested herein is mandatory and is maintained by the Dental Board of California (Board), 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, Executive Officer, 916-263-2300, in accordance with Business and Professions Code (BPC) sections1600 et seq. The Board collects the personal information requested on the following form as authorized by BPC sections 27, 30, 31, 114.5, 115.4, 135.4. 480, 494.5, 1646.1, 1646.2, 1646.9, 1715, and Title 16, California Code of Regulations sections 1043.1, 1043.3, and 1043.4. The Board uses this information to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Disclosure of your Social Security number is mandatory and collection is authorized by sections 29.5, 30, 31, and 494.5 of the Business & Professions Code and Pub. L 94-455 (42 U.S.C.A. § 405(c)(2)(C)). Your Social Security number will be used exclusively for tax enforcement purposes, for compliance with any judgment or order for family support in accordance with Section 17520 of the Family Code, measurement of employment outcomes of students who participate in career technical education programs offered by the California Community Colleges as required by BPC section 30, or for verification of licensure or examination status by a licensing or examination board, and where licensing is reciprocal with the requesting state. If you fail to disclose your Social Security number, you may be reported to the Franchise Tax Board and be assessed a penalty of $100.

Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure by the Information Practices Act, including Civil Code section 1798.40. The Board makes every effort to protect the personal information you provide us; however, it may be disclosed in response to a Public Records Act request as allowed by the Information Practices Act, to another government agency as required by state or federal law or Civil Code section 1798.24; or in response to a court or administrative order, a subpoena, or a search warrant. Your name and address listed on this application will be disclosed to the public upon request if and when you become licensed.

BUSINESS AND PROFESSIONS CODE § 1646.1. Requirements for administration of deep sedation or general anesthesia on outpatient basis; Requirements for administration to pediatric patients; Applicability [Operative January 1, 2022]
(a) A dentist shall possess either a current license in good standing and a general anesthesia permit issued by the board or a permit under Section 1638 or 1640 and a general anesthesia permit issued by the board in order to administer or order the administration of deep sedation or general anesthesia on an outpatient basis for dental patients.
(b) A dentist shall possess a pediatric endorsement of their general anesthesia permit to administer or order the administration of deep sedation or general anesthesia to patients under seven years of age. (c) A dentist shall be physically within the dental office at the time of ordering, and during the administration of, general anesthesia or deep sedation.
(d) For patients under 13 years of age, all of the following shall apply:
(1) The operating dentist and at least two additional personnel shall be
present throughout the procedure involving deep sedation or general anesthesia.
(2) If the operating dentist is the permitted anesthesia provider, then both of the following shall apply:
(A) The operating dentist and at least one of the additional personnel shall maintain current certification in Pediatric Advanced Life Support (PALS) or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8. The additional personnel who is certified in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management shall be solely dedicated to monitoring the patient and shall be trained to read and respond to monitoring equipment including, but not limited to, pulse oximeter, cardiac monitor, blood pressure, pulse, capnograph, and respiration monitoring devices.
(B) The operating dentist shall be responsible for initiating and administering any necessary emergency response.
(3) If a dedicated permitted anesthesia provider is monitoring the patient and administering deep sedation or general anesthesia, both of the following shall apply:
(A) The anesthesia provider and the operating dentist, or one other trained personnel, shall be present throughout the procedure and shall maintain 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.
(B) The anesthesia provider shall be responsible for initiating and administering any necessary emergency response and the operating dentist, or other trained and designated personnel, shall assist the anesthesia provider in
emergency response.
(e) This article does not apply to the administration of local anesthesia,
minimal sedation, or moderate sedation.
(Added Stats 2018 ch 929 § 4 (SB 501), effective January 1, 2019, operative January 1, 2022.)

§ 1646.2. General anesthesia permit application procedure and requirements; Pediatric endorsement requirements [Operative January 1, 2022]
(a) A dentist who desires to administer or order the administration of deep sedation or general anesthesia shall apply to the board on an application form prescribed by the board. The dentist must submit an application fee and produce evidence showing that he or she has 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.
(b) The application for a permit shall include documentation that equipment and drugs required by the board are on the premises.
(c) A dentist may apply for a pediatric endorsement for the general anesthesia permit by providing proof of successful completion of all of the following:
(1) 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.
(2) 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. The applicant or permitholder shall maintain and be able to provide proof of these cases upon request by the board for up to three permit renewal periods.
(3) 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.
(d) Applicants for a pediatric endorsement who otherwise qualify for the pediatric endorsement but lack sufficient cases of pediatric sedation to patients under seven years of age may administer deep sedation and general anesthesia to patients under seven years of age under the direct supervision of a general anesthesia permitholder with a pediatric endorsement. The applicant may count these cases toward the 20 cases required to qualify for the applicant's pediatric endorsement.
(Added Stats 2018 ch 929 § 4 (SB 501), effective January 1, 2019, operative January 1, 2022.)

§ 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.

(a) For the purposes of Sections 1646.2(c) and 1646.9 of the Code, submission of a completed application to the Board for a pediatric endorsement for a general anesthesia permit shall include the following information and documents:

(1) Name, mailing address or address of record, physical address, dental or medical license number, and applicant's general anesthesia permit number, if any;
(2) 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;
(3) A completed Form PE-1 (05/2021) "Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement," which is hereby incorporated by reference;
(4) A certificate or other documentary evidence 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);
(5) An application fee as set forth in section 1021; and,
(6) A certification, under penalty of perjury, by the applicant that the information on the application is true and correct.
(b) For the purpose of Section 1647.3(d) of the Code, submission of a completed application to the Board for a pediatric endorsement for a moderate sedation permit for patients under thirteen years of age shall include the following information and documents:
(1) Name, mailing address or address of record, physical address, dental license number, and applicant's moderate sedation permit number, if any;
(2) A certificate of completion or other documentary evidence showing completion of a residency training program as required by Section 1647.3 of the Code;
(3) A completed Form PE-1 as provided in this section;
(4) A certificate or other documentary evidence 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);
(~~6~~5) An application fee as set forth in section 1021; and,
(~~7~~6) A certification, under penalty of perjury, by the applicant that the information on the application is true and correct.
~~(c) 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..~~
(~~d~~c) Upon request by the Board in any investigation of the information provided on FormPE-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 signsthroughout the procedure, and condition at discharge.
(~~e~~d) Applicants shall submit legible copies of the information required by this section with pediatric patient identifying information redacted.
Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 27, 108, 1611.5, 1646.1, 1646.2, 1647.2 and 1647.3, 1646.9, Business and Professions Code.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DENTAL BOARD OF CALIFORNIA
2005 Evergreen St., Suite 1550, Sacramento, CA 95815
P (916) 263-2300 | F (916) 263-2140 | www.dbc.ca.gov

APPLICATION FOR MODERATE SEDATION PERMIT

FEES Application Fee: $524.00 (Must be enclosed with application) **APPLICATION FEES ARE NON-REFUNDABLE**	*For Office Use Only* Rec # _____ Fee Pd _____ Date Cashiered _____ Entity# _____ File # _____	*For Office Use Only* Date Received

*This application must be completed in its entirety or the application may be rejected as incomplete. Attach additional sheets if necessary.
* Any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit.
* Under Business and Professions Code sections 31 and 494.5, the ~~State Board of Equalization (BOE)~~ California Department of Tax and Fee Administration (CDTFA) and the Franchise Tax Board (FTB) may share taxpayer information with the Board. You are required to pay your state tax obligation. This application may be denied or your permit may be suspended if you have a state tax obligation and the state tax obligation is not paid and your name appears on ~~either~~ the ~~BOE~~ State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

(PLEASE PRINT CLEARLY OR TYPE)

1. SSN/ITIN:	2. BIRTH DATE (MM/DD/YYYY):
3. LEGAL NAME: LAST FIRST MIDDLE	
4. MAILING ADDRESS (ADDRESS OF RECORD -- ADDRESS MAY BE A P.O. BOX):	
5. PRIMARY PRACTICE LOCATION (PHYSICAL ADDRESS)	
6. EMAIL ADDRESS [OPTIONAL):	
7. TELEPHONE NUMBER:	
8. FAX NUMBER [OPTIONAL]	

9. DENTAL LICENSE NUMBER:	
10. **MODERATE SEDATION TRAINING**. HAVE YOU SUCCESSFULLY COMPLETED TRAINING IN MODERATE SEDATION? FOR PURPOSES OF THIS SECTION, TRAINING CONSISTS OF ALL OF THE FOLLOWING: (1) 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) COMPLIES 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. IF YES, PLEASE SUBMIT A COMPLETED "CERTIFICATION OF MODERATE SEDATION TRAINING" (MSP-2 (New 05/21) WITH THIS APPLICATION.	YES ☐ NO ☐
11. IN ADDITION TO THE MODERATE SEDATION PERMIT, ARE YOU APPLYING FOR A PEDIATRIC ENDORSEMENT TO ADMINSTER MODERATE SEDATION TO A PEDIATRIC PATIENT UNDER 13 YEARS OF AGE? IF YOU ANSWERED "YES" TO THIS QUESTION, YOU MUST COMPLETE A SEPARATE APPLICATION FOR A PEDIATRIC ENDORSEMENT AND MEET THE REQUIREMENTS IN SECTION 1043.8.1 OF TITLE 16 OF THE CALIFORNIA CODE OF REGULATIONS. YOU MAY APPLY FOR A PEDIATRIC ENDORSEMENT SIMULTANEOUSLY BY SUBMITTING BOTH APPLICATIONS AT THE SAME TIME. YOU MAY ALSO APPLY SEPARATELY FOR A PEDIATRIC ENDORSEMENT AT A LATER DATE BY COMPLETING THE APPLICATION AND MEETING THE REQUIREMENTS IN SECTION 1043.8.1. NOTICE: PLEASE SEE ATTACHED MONITORING REQUIREMENTS IN BUSINESS AND PROFESSIONS CODE, SECTION 1647.2, 1647.3, AND CALIFORNIA CODE OF REGULATIONS, TITLE 16, SECTION 1043.8.1. PLEASE CHECK THIS BOX IF YOU WOULD LIKE THE PEDIATRIC ENDORSEMENT APPLICATION PROCESSED ALONG WITH THIS APPLICATION: ☐	YES ☐ NO ☐
12. ARE YOU SERVING IN, OR HAVE YOU PREVIOUSLY SERVED IN, THE U.S. MILITARY?	YES ☐ NO ☐
13. ARE YOU REQUESTING EXPEDITING OF THIS APPLICATION FOR HONORABLYDISCHARGED MEMBERS OF THE U.S. ARMED FORCES? *MILITARY HONORABLE DISCHARGE REQUIREMENTS* NOTE: PLEASE SCAN AND ATTACH A COPY OF THE FOLLOWING DOCUMENTATION ON THE ATTACHMENTS PAGE OF THIS APPLICATION: CERTIFICATE OF RELEASE OR DISCHARGE FROM ACTIVE DUTY (DD-214) OR OTHER DOCUMENTARY EVIDENCE SHOWING DATE AND TYPE OF DISCHARGE TO RECEIVE EXPEDITED REVIEW.	YES ☐ NO ☐

14. DO YOU ALREADY HOLD A VALID LICENSE, OR COMPARABLE AUTHORITY, TO PRACTICE DENTISTRY IN ANOTHER U.S. STATE OR TERRITORY, AND YOUR SPOUSE OR DOMESTIC PARTNER IS AN ACTIVE DUTY MEMBER OF THE ARMED FORCES OF THE UNITED STATES AND WAS ASSIGNED TO A DUTY STATION IN CALIFORNIA UNDER OFFICIAL ORDERS? IF YES, YOUR APPLICATION WILL RECEIVE AN EXPEDITED REVIEW. *MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENTS* NOTE: IF YOU MEET THE MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENT PLEASE SCAN AND ATTACH THE FOLLOWING DOCUMENTATION ON THE ATTACHMENTS PAGE OF THIS APPLICATION: • 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 • A COPY OF YOUR CURRENT DENTAL LICENSE IN ANOTHER STATE, DISTRICT, OR TERRITORY OF THE UNITED STATES. • A COPY OF THE MILITARY ORDERS ESTABLISHING YOUR SPOUSE OR PARTNER'S DUTY STATION IN CALIFORNIA	YES ☐ NO ☐
15. DO ANY OF THE FOLLOWING STATEMENTS APPLY TO YOU: • YOU WERE ADMITTED TO THE UNITED STATES AS A REFUGEE PURSUANT TO SECTION 1157 OF TITLE 8 OF THE UNITED STATES CODE; • YOU WERE 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, • YOU HAVE A SPECIAL IMMIGRANT VISA AND WERE 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]. IF YOU SELECTED YES, YOU MUST ATTACH EVIDENCE OF YOUR STATUS AS A REFUGEE, ASYLEE, OR SPECIAL IMMIGRANT VISA HOLDER AS PROVIDED BELOW. FAILURE TO DO SO MAY RESULT IN APPLICATION PROCESSING DELAYS. "EVIDENCE" SHALL INCLUDE: • 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" • 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 THATTHE APPLICANT QUALIFIES FOR EXPEDITED LICENSURE PER BUSINESS AND PROFESSIONS CODE SECTION 135.4.	YES ☐ NO ☐

FACILITIES AND EQUIPMENT REQUIREMENTS - ALL EQUIPMENT SHOULD BE MAINTAINED, TESTED, AND INSPECTED ACCORDING TO THE MANUFACTURERS' SPECIFICATIONS. IN AN OFFICE WHERE SEDATION SERVICES ARE TO BE PROVIDED TO PEDIATRIC PATIENTS, THE REQUIRED EQUIPMENT, MEDICATION AND RESUSCITATIVE CAPABILITIES SHALL BE APPROPRIATELY SIZED FOR USE ON A PEDIATRIC POPULATION.	
16. DOES THE FACILITY HAVE AN OPERATING THEATER LARGE ENOUGH TO ADEQUATELY ACCOMMODATE THE PATIENT ON A TABLE OR IN AN OPERATING CHAIR AND PERMIT AN OPERATING TEAMCONSISTING OF AT LEAST THREE INDIVIDUALS TO FREELY MOVE ABOUT THE PATIENT?	YES ☐ NO ☐
17. DOES THE FACILITY HAVE 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 PROVIDE A FIRM PLATFORM FOR THE MANAGEMENT OF CARDIOPULMONARY RESUSCITATION?	YES ☐ NO ☐
18. DOES 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 OFANY OPERATION UNDERWAY AT THE TIME OF GENERAL POWER FAILURE?	YES ☐ NO ☐
19. DOES THE FACILITY HAVE SUCTION EQUIPMENT THAT PERMITS ASPIRATION OF THE ORAL AND PHARYNGEAL CAVITIES AND A BACKUP SUCTION DEVICE THAT CAN OPERATE AT THE TIME OF GENERAL POWER FAILURE?	YES ☐ NO ☐
20. DOES THE FACILITY HAVE 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 THEPATIENT UNDER POSITIVE PRESSURE, TOGETHER WITH AN ADEQUATE BACKUP SYSTEM THAT CAN OPERATE AT THE TIME OF GENERAL POWER FAILURE?	YES ☐ NO ☐
21. DOES THE FACILITY HAVE A RECOVERY AREA THAT HAS AVAILABLE OXYGEN, ADEQUATE LIGHTING, SUCTION AND ELECTRICAL OUTLETS? THE RECOVERY AREA CAN BE THE OPERATING THEATER.	YES ☐ NO ☐
22. ANCILLARY EQUIPMENT MAINTAINED IN GOOD OPERATING CONDITION, WHICH MUST INCLUDE ALL OF THE FOLLOWING: (a) EMERGENCY AIRWAY EQUIPMENT (ORAL AIRWAYS, LARYNGEAL MASK AIRWAYS OR COMBITUBES, CRICOTHYROTOMY DEVICE). (b) TONSILLAR OR PHARYNGEAL TYPE SUCTION TIPS ADAPTABLE TO ALL OFFICE OUTLETS. (c) SPHYGMOMANOMETER AND STETHOSCOPE. (d) ADEQUATE EQUIPMENT FOR THE ESTABLISHMENT OF AN INTRAVENOUS INFUSION. (e) PRECORDIAL/PRETRACHEAL STETHOSCOPE. (f) PULSE OXIMETER (g) CAPNOGRAPH AND TEMPERATURE DEVICE. PATIENTS RECEIVING MODERATE SEDATION SHALL HAVE VENTILATION CONTINUOUSLY MONITORED DURING THE PROCEDURE BY TWO OF THE FOLLOWING THREE METHODS: (I) AUSCULTATION OF BREATH SOUNDS USING A PRECORDIAL STETHOSCOPE. (II) MONITORING FOR THE PRESENCE OF EXHALED CARBON DIOXIDE WITH CAPNOGRAPHY. (III) VERBAL COMMUNICATION WITH A PATIENT UNDER MODERATE SEDATION.	YES ☐ NO ☐

RECORDS - DO YOU MAINTAIN THE FOLLOWING RECORDS?	
23. ADEQUATE MEDICAL HISTORY AND PHYSICAL EVALUATION RECORDS UPDATED PRIOR TO EACH ADMINISTRATION OF MODERATE SEDATION. SUCH RECORDS SHALL INCLUDE BUT ARE NOT LIMITED TO THE RECORDING OF THE AGE, SEX, WEIGHT, PHYSICAL STATUS (AMERICAN SOCIETY OF ANESTHESIOLOGISTS CLASSIFICATION), MEDICATION USE, ANY KNOWN OR SUSPECTED MEDICALLY COMPROMISING CONDITIONS, RATIONALE FOR SEDATION OF THE PATIENT, AND AN EVALUATION OF THE AIRWAY	YES ☐ NO ☐
24. MODERATE SEDATION RECORDS, WHICH SHALL 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.	YES ☐ NO ☐
25. RECORDS INCLUDING 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.	YES ☐ NO ☐
26. WRITTEN INFORMED CONSENT OF THE PATIENT, OR, AS APPROPRIATE, PATIENT'S CONSERVATOR, OR THE INFORMED CONSENT OF A PERSON AUTHORIZED TO GIVE SUCH CONSENT FOR THE PATIENT, OR IF THE PATIENT IS A MINOR, ~~OR~~ HIS OR HER PARENT OR GUARDIAN, PURSUANT TO BUSINESS AND PROFESSIONS CODE SECTION 1682(e).	YES ☐ NO ☐
27. **DRUGS** - DO YOU MAINTAIN EMERGENCY DRUGS OF THE FOLLOWING TYPES AT ALL TIMES IN CONNECTION WITH THE ADMINISTRATION OF MODERATE SEDATION? • EPINEPHRINE (EPI) • VASOPRESSOR (OTHER THAN EPI) • BRONCHODILATOR • APPROPRIATE DRUG ANTAGONIST • ANTIHISTAMINIC • ANTICHOLINGERGIC • CORONARY ARTERY VASODILATOR • ANTICONVULSANT • OXYGEN • 50% DEXTROSE OR OTHER ANTIHYPOGLYCEMIC	YES ☐ NO ☐
28. **EMERGENCIES** - ARE YOU COMPETENT TO TREAT ALL OF THE FOLLOWING EMERGENCIES? • AIRWAY OBSTRUCTION • BRONCHOSPASM • EMESIS AND ASPIRATION OF FOREIGN MATERIAL UNDER ANESTHESIA • ANGINA PECTORIS • MYOCARDIAL INFARCTION • HYPOTENSION • HYPERTENSION • CARDIAC ARREST • ALLERGIC REACTION • CONVULSIONS • HYPOGLYCEMIA • SYNCOPE • RESPIRATORY DEPRESSION	YES ☐ NO ☐
29. **STAFF**- ARE DENTAL OFFICE PERSONNEL DIRECTLY INVOLVED WITH THE CARE OF PATIENTS UNDERGOING MODERATE SEDATION CERTIFIED IN BASIC CARDIAC LIFE SUPPORT (CPR)?	YES ☐ NO ☐

30. PROVIDE THE ADDRESSES OF ALL LOCATIONS OF PRACTICE WHERE YOU ADMINISTER OR ORDER THE ADMINISTRATION OF MODERATE SEDATION. ALL OFFICES SHALL 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.

_____

_____

_____

IF NECESSARY, CONTINUE ON THE BACK OF THIS PAGE.

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing information, including any attachments, is true and correct.

_____

Date

Signature of Applicant

INFORMATION COLLECTION AND ACCESS Except for the email address and fax number, the information requested herein is mandatory and is maintained by the Dental Board of California (Board), 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, Executive Officer, 916-263-2300, in accordance with Business and Professions Code (BPC)sections1600 et seq. The Board collects the personal information requested on the following form as authorized by BPC sections 27, 30, 31, 114.5, 115.4, 135.4, 480, 494.5, 1647.2, 1647.3, 1715, and Title 16, California Code of Regulations sections 1043.1, 1043.3, and 1043.4. The Board uses this information to identify and evaluate applicants for permit or licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Disclosure of your Social Security number is mandatory and collection is authorized by sections 29.5, 30, 31, and 494.5 of the Business & Professions Code and Pub. L 94-455 (42 U.S.C.A. § 405(c)(2)(C)). Your Social Security number will be used exclusively for tax enforcement purposes, for compliance with any judgment or order for family support in accordance with Section 17520 of the Family Code, measurement of employment outcomes of students who participate in career technical education programs offered by the California Community Colleges as required by BPC section 30, or for verification of licensure or examination status by a licensing or examination board, and where licensing is reciprocal with the requesting state. If you fail to disclose your Social Security number, you may be reported to the Franchise Tax Board and be assessed a penalty of $100.

Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure by the Information Practices Act, including Civil Code section 1798.40. The Board makes every effort to protect the personal information you provide us; however, it may be disclosed in response to a Public Records Act request as allowed by the Information Practices Act, to another government agency as required by state or federal law or Civil Code section 1798.24; or in response to a court or administrative order, a subpoena, or a search warrant. Your name and address listed on this application will be disclosed to the public upon request if and when you become licensed.

BUSINESS AND PROFESSIONS CODE § 1647.2. Requirements for administration of moderate sedation on outpatient basis; Requirements for administration to pediatric patients; Applicability [Operative January 1, 2022]

(a) A dentist may administer or order the administration of moderate sedation on an outpatient basis for a dental patient if one of the following conditions is met:

(1) The dentist possesses a current license in good standing and either holds a valid general anesthesia permit or obtains a moderate sedation permit.

(2) The dentist possesses a current permit under Section 1638 or 1640 and either holds a valid general anesthesia permit or obtains a moderate sedation permit.

(b) A dentist shall obtain a pediatric endorsement on the moderate sedation permit prior to administering moderate sedation to a patient under 13 years of age.

(c)(1) A dentist who orders the administration of moderate sedation shall be physically present in the treatment facility while the patient is sedated.

(2) For patients under 13 years of age, there shall be at least two support personnel in addition to the operating dentist present at all times during the procedure involving moderate sedation. The operating dentist and one personnel member shall maintain 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. The personnel member with current certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management shall be dedicated to monitoring the patient during the procedure involving moderate sedation and may assist with interruptible patient-related tasks of short duration, such as holding an instrument.

(d) A dentist with a moderate sedation permit or a moderate sedation permit with a pediatric endorsement shall possess the training, equipment, and supplies to rescue a patient from an unintended deeper level of sedation.

(e) This article shall not apply to the administration of local anesthesia, minimal sedation, deep sedation, or general anesthesia.

(Added Stats 2018 ch 929 § 6 (SB 501), effective January 1, 2019, operative January 1, 2022.)

§ 1647.3. Moderate sedation permit application procedure and requirements; Pediatric endorsement requirements [Operative January 1, 2022]

(a) 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. The dentist shall submit an application fee and produce evidence showing that he or she has successfully completed training in moderate sedation that meets the requirements of subdivision (c).

(b) The application for a permit shall include documentation that equipment and drugs required by the board are on the premises.

(c) Training in the administration of moderate sedation shall be acceptable if it meets all of the following as approved by the board:

(1) Consists of at least 60 hours of instruction.

(2) Requires satisfactory completion of at least 20 cases of administration of moderate sedation for a variety of dental procedures.

(3) Complies 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.

(d) A dentist may apply for a pediatric endorsement for a moderate sedation permit by confirming all of the following:

(1) Successful completion of 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.

(2) Successful completion of at least 20 cases of moderate sedation to patients under 13 years of age to establish competency in pediatric moderate sedation, both at the time of the initial application and at renewal. The applicant or permitholder shall maintain and shall provide proof of these cases upon request by the board for up to three permit renewal periods.

(3) In order to provide moderate sedation to children under seven years of age, a dentist shall 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 and for each permit renewal period.

(4) 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.

(e) A permitholder shall maintain current and continuous 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, for the duration of the permit.

(f) Applicants for a pediatric endorsement who otherwise qualify for the pediatric endorsement but lack sufficient cases of moderate sedation to patients under 13 years of age may administer moderate sedation to patients under 13 years of age under the direct supervision of a general anesthesia or moderate sedation permitholder with a pediatric endorsement. The applicant may count these cases toward the 20 required in order to qualify for the applicant's pediatric endorsement.

(g) Moderate sedation permit holders with 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 pursuant to paragraph (3) of subdivision (d), may administer moderate sedation to patients under seven years of age under the direct supervision of a permitholder who meets those qualifications.

(Added Stats 2018 ch 929 § 6 (SB 501), effective January 1, 2019, operative January 1, 2022.)

§ 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.

(a) For the purposes of Sections 1646.2(c) and 1646.9 of the Code, submission of a completed application to the Board for a pediatric endorsement for a general anesthesia permit shall include the following information and documents:

(1) Name, mailing address or address of record, physical address, dental or medical license number, and applicant's general anesthesia permit number, if any;

(2) 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;

(3) A completed Form PE-1 (05/2021) “Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement,” which is hereby incorporated by reference;
(4) A certificate or other documentary evidence 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);
(5) An application fee as set forth in section 1021; and,
(6) A certification, under penalty of perjury, by the applicant that the information on the application is true and correct.
(b) For the purpose of Section 1647.3(d) of the Code, submission of a completed application to the Board for a pediatric endorsement for a moderate sedation permit for patients under thirteen years of age shall include the following information and documents:
(1) Name, mailing address or address of record, physical address, dental license number, and applicant’s moderate sedation permit number, if any;
(2) A certificate of completion or other documentary evidence showing completion of a residency training program as required by Section 1647.3 of the Code;
(3) A completed Form PE-1 as provided in this section;
(4) A certificate or other documentary evidence 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);
(~~6~~5) An application fee as set forth in section 1021; and,
(~~7~~6) A certification, under penalty of perjury, by the applicant that the information on the application is true and correct.
~~(c) 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..~~
(~~d~~c) Upon request by the Board in any investigation of the information provided on FormPE-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 signsthroughout the procedure, and condition at discharge.
(~~e~~d) Applicants shall submit legible copies of the information required by this section with pediatric patient identifying information redacted.
Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 27, 108, 1611.5, 1646.1, 1646.2, 1647.2 and 1647.3, 1646.9, Business and Professions Code.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DENTAL BOARD OF CALIFORNIA
2005 Evergreen St., Suite 1550, Sacramento, CA 95815
P (916) 263-2300 | F (916) 263-2140 | www.dbc.ca.gov

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 Business and Professions Code section 1647.3 and Title 16 CCR section 1043.1. The information provided will be used to determine qualification for a moderate sedation permit. 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.

(APPLICANT TO COMPLETE QUESTIONS 1-3 AND EDUCATIONAL INSTITUTION TO COMPLETE QUESTION 4)

1. LEGAL NAME: LAST FIRST MIDDLE

2. LICENSE NUMBER:

3. NAME OF SCHOOL/EDUCATIONAL INSTITUTION:

4. MODERATE SEDATION TRAINING VERIFICATION:

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

☐ AT LEAST 60 HOURS OF INSTRUCTION

☐ REQUIRES SATISFACTORY COMPLETION OF AT LEAST 20 CASES OF ADMINISTRATION OF MODERATE SEDATION FOR A VARIETY OF DENTAL PROCEDURES.

☐ COMPLIES 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 PATIENT FROM A DEEPER LEVEL OF SEDATION THAN INTENDED, AND MANAGING THE AIRWAY, INTRAVASCULAR OR INTRAOSSEOUS ACCESS, AND REVERSAL MEDICATIONS

I HEREBY CERTIFY THAT THE INFORMATION PROVIDED IN THIS SECTION OF THE FORM IS TRUE AND CORRECT AND CONFIRM THAT, ACCORDING TO THIS INSTITUTION'S RECORDS, _____ (NAME OF STUDENT) SATISFACTORILY COMPLETED THE ABOVE-REFERENCED TRAINING AT _____ (NAME OF INSTITUTION). THIS STUDENT WAS ENROLLED IN A _____ (NAME OF PROGRAM) PROGRAM WHEN OBTAINING MODERATE SEDATION TRAINING FROM _____ (MONTH/DAY/YEAR) TO _____ (MONTH/DAY/YEAR).

EDUCATIONAL PROGRAM SEAL (IF APPLICABLE)

_____
SIGNATURE DATE

_____
PRINTED NAME/TITLE TELEPHONE

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DOCUMENTATION OF DEEP SEDATION AND GENERAL ANESTHESIA OR MODERATE SEDATION CASES FOR PEDIATRIC ENDORSEMENT

This document shall be completed in its entirety as part of the initial application for a pediatric endorsement (for both general anesthesia and moderate sedation permits) or as a condition of the renewal application for ~~either~~ a general anesthesia ~~or moderate sedation~~ permit that includes a pediatric endorsement as provided in Section 1017.1 of Title 16 of the California Code of Regulations (16 CCR) or your application may be rejected as incomplete. The requirements for a completed initial application for a pediatric endorsement to a general anesthesia permit or a moderate sedation permit are listed in 16 CCR section 1043.~~1.8~~.8.1. Attach additional sheets to this form as necessary. Any material misrepresentation of any information on this form is grounds for denial or subsequent revocation of the permit.

The information requested on this form is mandatory pursuant to Business and Professions Code sections 1646.2 and 1647.3 and Title 16 CCR section 1043. .~~1.8~~.8.1. The information provided will be used to determine qualifications for a pediatric endorsement to a general anesthesia or moderate sedation permit. 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 92815, Executive Officer, 916-263-2300.

Notice for General Anesthesia Permit Applicants Seeking Pediatric Endorsement or Renewal of Endorsement:

All applicants must meet the patient monitoring and staff qualification requirements listed in Section 1646.1 of the Business and Professions Code.

Each 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. The applicant or permitholder shall maintain and be able to provide proof of these cases upon request by the board for up to three permit renewal periods.

Applicants for a pediatric endorsement who otherwise qualify for the pediatric endorsement but lack sufficient cases of pediatric sedation to patients under seven years of age may administer deep sedation and general anesthesia to patients under seven years of age under the direct supervision of a general anesthesia permitholder with a pediatric endorsement. The applicant may count these cases toward the 20 cases required to qualify for the applicant's pediatric endorsement. (Business and Professions Code section 1646.2.)

Notice for Moderate Sedation Permit Applicants Seeking Pediatric Endorsement or Renewal of Endorsement:

All applicants must meet the patient monitoring and staff qualification requirements listed in Section 1647.2 of the Business and Professions Code.

Each applicant must provide proof of successful completion of at least 20 cases of moderate sedation to patients under 13 years of age to establish competency in pediatric moderate sedation, both at the time of the initial application and at renewal. The applicant or permitholder shall maintain and shall provide proof of these cases upon request by the board for up to three permit renewal periods.

In order to provide moderate sedation to children under seven years of age, a dentist shall 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 and for each permit renewal period.

Applicants for a pediatric endorsement who otherwise qualify for the pediatric endorsement but lack sufficient cases of moderate sedation to patients under 13 years of age may administer moderate sedation to patients under 13 years of age under the direct supervision of a general anesthesia or moderate sedation permitholder with a pediatric endorsement. The applicant may count these cases toward the 20 required in order to qualify for the applicant's pediatric endorsement.

Moderate sedation permit holders with 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 pursuant to paragraph (3) of subdivision (d), may administer moderate sedation to patients under seven years of age under the direct supervision of a permitholder who meets those qualifications. (Business and Professions Code section 1647.3.)

1. APPLICANT'S LEGAL NAME: LAST FIRST MIDDLE

2. MEDICAL OR DENTAL LICENSE NUMBER:

3. SPECIFY THE TYPE OF PEDIATRIC ENDORSEMENT YOU ARE REQUESTING.

☐ DEEP SEDATION AND GENERAL ANESTHESIA FOR PEDIATRIC PATIENTS UNDER 7.
- (FOR GENERAL ANESTHESIA PERMIT APPLICATION)

☐ MODERATE SEDATION FOR PEDIATRIC PATIENTS UNDER THE AGE OF 13.
- (FOR MODERATE SEDATION PERMIT APPLICATION)

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

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

A. ARE YOU SEEKING TO PROVIDE MODERATE SEDATION TO CHILDREN UNDER THIRTEEN YEARS OF AGE?

YES ____ NO ____

B. IF YES TO QUESTION 5~~4~~.A., PLEASE CHECK ALL THAT APPLY:

☐ I COMPLETED AT LEAST 20 CASES OF MODERATE SEDATION FOR CHILDREN UNDER THIRTEEN YEARS OF AGE AS NOTED ON THIS FORM OR RELATED ATTACHMENTS

☐ I COMPLETED AT LEAST 20 CASES OF MODERATE SEDATION FOR CHILDREN UNDER THIRTEEN YEARS OF AGE UNDER DIRECT SUPERVISION BY ANOTHER PERMITHOLDER AS NOTED ON THIS FORM OR RELATED ATTACHMENTS

☐ I COMPLETED AT LEAST 20 CASES OF MODERATE SEDATION FOR CHILDREN UNDER THIRTEEN YEARS OF AGE BOTH INDEPENDENTLY AND UNDER DIRECT SUPERVISION BY ANOTHER PERMITHOLDER AS NOTED ON THIS FORM OR RELATED ATTACHMENTS

~~5~~6. A. ARE YOU SEEKING TO PROVIDE MODERATE SEDATION TO CHILDREN UNDER SEVEN YEARS OF AGE?

YES ____ NO ____

B. IF YES TO QUESTION ~~5~~6.A., PLEASE CHECK ONE OF THE FOLLOWING:

☐ I COMPLETED AT LEAST 20 CASES OF MODERATE SEDATION FOR CHILDREN UNDER SEVEN YEARS OF AGE AS NOTED ON THIS FORM OR RELATED ATTACHMENTS.

☐ I DID NOT COMPLETE AT LEAST 20 TOTAL CASES OF MODERATE SEDATION FOR CHILDREN UNDER SEVEN YEARS OF AGE INDEPENDENTLY BUT I ADMINISTER MODERATE SEDATION TO PATIENTS UNDER SEVEN YEARS OF AGE UNDER THE DIRECT SUPERVISION OF A PERMITHOLDER WHO MEETS THOSE QUALIFICATIONS.

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

CASE 1	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: ☐ DS ☐ GA ☐ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 2	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: ☐ DS ☐ GA ☐ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 3	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 4	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 5	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 6	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 7	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 8	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 9	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 10	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 11	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 12	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 13	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 14	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 15	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 16	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

CASE 17	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 18	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS)	TYPE OF PROCEDURE:

CASE 19		PROCEDURE: □ DS □ GA □ MS	
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		
CASE 20	DATE OF PROCEDURE:	DEEP SEDATION (DS), GENERAL ANESTHESIA (GA), OR MODERATE SEDATION (MS) PROCEDURE: □ DS □ GA □ MS	TYPE OF PROCEDURE:
	PEDIATRIC PATIENT AGE:	PEDIATRIC PATIENT SEX:	PEDIATRIC PATIENT WEIGHT:
	BRIEFLY DESCRIBE THE METHOD, AMOUNT, AND SPECIFIC SEDATION AGENT ADMINISTERED: WHO ADMINISTERED THE SEDATION, WHO MONITORIED THE PATIENT AND WHO PERFORMED THE PROCEDURE:		
	PLEASE DESCRIBE PEDIATRIC PATIENT'S CONDITION AT DISCHARGE:		

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing information, including all attachments, is true and correct.

_____

Date Signature of Applicant

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
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APPLICATION FOR PEDIATRIC MINIMAL SEDATION PERMIT

FEES	*For Office Use Only*	*For Office Use Only*
Application Fee: $459.00 (Must be enclosed with application) **APPLICATION FEES ARE NON-REFUNDABLE**	Rec # _____ Fee Pd _____ Date Cashiered _____ Entity# _____ File # _____	Date Received

*This application must be completed in its entirety or the application may be rejected as incomplete. Attach additional sheets if necessary.
* Any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit.
* Under Business and Professions Code sections 31 and 494.5, the ~~State Board of Equalization (BOE)~~California Department of Tax and Fee Administration (CDTFA) and the Franchise Tax Board (FTB) may share taxpayer information with the Board. You are required to pay your state tax obligation. This application may be denied or your permit may be suspended if you have a state tax obligation and the state tax obligation is not paid and your name appears on ~~either~~ the ~~BOE~~State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.
*Please include your "Certification of Pediatric Minimal Sedation Training" (Form PMSP-2(new 05/21) and fee with this application.

(PLEASE PRINT CLEARLY OR TYPE)

1. SSN/ITIN:	2. BIRTH DATE (MM/DD/YYYY):
3. LEGAL NAME: LAST FIRST MIDDLE	
4. MAILING ADDRESS (ADDRESS OF RECORD – ADDRESS MAY BE A P.O. BOX):	
5. PRIMARY PRACTICE LOCATION (PHYSICAL ADDRESS):	
6. EMAIL ADDRESS (OPTIONAL):	
7. TELEPHONE NUMBER:	
8. FAX NUMBER (OPTIONAL)	

9. DENTAL LICENSE NUMBER:	
10. ARE YOU SERVING IN, OR HAVE YOU PREVIOUSLY SERVED IN, THE U.S. MILITARY?	YES ☐ NO ☐
11. ARE YOU REQUESTING EXPEDITING OF THIS APPLICATION FOR HONORABLY DISCHARGED MEMBERS OF THE U.S. ARMED FORCES? *MILITARY HONORABLE DISCHARGE REQUIREMENTS* NOTE: PLEASE SCAN AND ATTACH A COPY OF THE FOLLOWING DOCUMENTATION CERTIFICATE OF RELEASE OR DISCHARGE FROM ACTIVE DUTY (DD-214) OR OTHER DOCUMENTARY EVIDENCE SHOWING DATE AND HONORABLE DISCHARGE TO RECEIVE EXPEDITED REVIEW.	YES ☐ NO ☐
12. DO YOU ALREADY HOLD A VALID LICENSE, OR COMPARABLE AUTHORITY, TO PRACTICE DENTISTRY IN ANOTHER U.S. STATE OR TERRITORY, AND YOUR SPOUSE OR DOMESTIC PARTNER IS AN ACTIVE DUTY MEMBER OF THE ARMED FORCES OF THE UNITED STATES AND WAS ASSIGNED TO A DUTY STATION IN CALIFORNIA UNDER OFFICIAL ORDERS? IF YES, YOUR APPLICATION WILL RECEIVE AN EXPEDITED REVIEW. *MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENTS* NOTE: IF YOU MEET THE MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENT PLEASE SCAN AND ATTACH THE FOLLOWING DOCUMENTATION ON THE ATTACHMENTS PAGE OF THIS APPLICATION: • 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 • A COPY OF YOUR CURRENT DENTAL LICENSE IN ANOTHER STATE, DISTRICT, OR TERRITORY OF THE UNITED STATES. • A COPY OF THE MILITARY ORDERS ESTABLISHING YOUR SPOUSE OR PARTNER'S DUTY STATION IN CALIFORNIA	YES ☐ NO ☐

13. DO ANY OF THE FOLLOWING STATEMENTS APPLY TO YOU: • YOU WERE ADMITTED TO THE UNITED STATES AS A REFUGEE PURSUANT TO SECTION 1157 OF TITLE 8 OF THE UNITED STATES CODE; • YOU WERE GRANTED ASYLUM BY THE SECRETARY OF HOMELAND SECURITY OR THE ATTORNEY GENERAL OF THE UNITED STATES PURSUANT TO SECTION 1158 OFTITLE 8 OF THE UNITED STATES CODE; OR, • YOU HAVE A SPECIAL IMMIGRANT VISA AND WERE 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]. IF YOU SELECTED YES, YOU MUST ATTACH EVIDENCE OF YOUR STATUS AS A REFUGEE, ASYLEE, OR SPECIAL IMMIGRANT VISA HOLDER AS PROVIDED BELOW. FAILURE TO DO SO MAY RESULT IN APPLICATION PROCESSING DELAYS. “EVIDENCE” SHALL INCLUDE: • 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” • 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 THATTHE APPLICANT QUALIFIES FOR EXPEDITED LICENSURE PER BUSINESS AND PROFESSIONS CODE SECTION 135.4.	YES ☐ NO ☐

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

14. DOES THE FAC~~I~~ILITY HAVE:

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) ANCILLARY EQUIPMENT, WHICH MUST INCLUDE THE FOLLOWING, AND BE MAINTAINED IN GOOD OPERATING CONDITION:

(1) ORAL AIRWAYS CAPABLE OF ACCOMMODATING PEDIATRIC PATIENTS OF ALL SIZES.

(2) A SPHYGMOMANOMETER WITH CUFFS OF APPROPRIATE SIZE FOR PEDIATRIC PATIENTS OF ALL SIZES.

(3) A PRECORDIAL/PRETRACHEAL STETHOSCOPE.

(4) A PULSE OXIMETER.

YES ☐

NO ☐

15. DO YOU MAINTAIN THE FOLLOWING RECORDS? (1) 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. (2) 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. (3) DOCUMENTATION THAT ALL EMERGENCY EQUIPMENT IS CHECKED AND MAINTAINED TO DETERMINE OPERABILITY AND SAFETY FOR THE PATIENT CONSISTENT WITH MANUFACTURER'S RECOMMENDATIONS. (4) 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.	YES ☐ NO ☐
16. DO YOU HAVE AVAILABLE AND READILY ACCESSIBLE AN EMERGENCY KIT OR CART THAT INCLUDES THE FOLLOWING ITEMS? (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. (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	YES ☐ NO ☐
17. STAFF: ARE YOU AND AT LEAST ONE STAFF MEMBER TRAINED IN THE MONITORING AND RESUSCITATION OF PEDIATRIC PATIENTS? (TRAINED STAFF ARE REQUIRED TO BE PRESENT DURING THE ADMINISTRATION OF MINIMAL SEDATION PER BUSINESS AND PROFESSIONS CODE SECTION 1647.32.)	YES ☐ NO ☐
18. DID YOU OBTAIN A WRITTEN INFORMED CONSENT FROM THE PARENT OR GUARDIAN OF THE MINOR PATIENT PRIOR TO EACH ADMINISTRATION OF PEDIATRIC MINIMAL SEDATION?	YES ☐ NO ☐

19. PROVIDE THE ADDRESSES OF ALL LOCATIONS OF PRACTICE WHERE YOU ADMINISTER OR ORDER THE ADMINISTRATION OF PEDIATRIC MINIMAL SEDATION. 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.

_____

_____

_____

IF NECESSARY, CONTINUE ON THE BACK OF THIS PAGE.

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing information, including any attachments, is true and correct.

_____

Date Signature of Applicant

INFORMATION COLLECTION AND ACCESS: Except for the email address and fax number, the information requested herein is mandatory and is maintained by the Dental Board of California (Board), 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, Executive Officer, 916-263-2300, in accordance with Business and Professions Code (BPC)sections1600 et seq. The Board collects the personal information requested on the following form as authorized by BPC sections 27, 30, 31, 114.5, 115.4, 135.4, 480, 494.5, 1647.31, 1647.32, 1647.33, 1715, and Title 16, California Code of Regulations sections 1043.9.1 and 1043.9.2. The Board uses this information to identify and evaluate applicants for permit or licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Disclosure of your Social Security number is mandatory and collection is authorized by sections 29.5, 30, 31, and 494.5 of the Business & Professions Code and Pub. L 94-455 (42 U.S.C.A. § 405(c)(2)(C)). Your Social Security number will be used exclusively for tax enforcement purposes, for compliance with any judgment or order for family support in accordance with Section 17520 of the Family Code, measurement of employment outcomes of students who participate in career technical education programs offered by the California Community Colleges as required by BPC section 30, or for verification of licensure or examination status by a licensing or examination board, and where licensing is reciprocal with the requesting state. If you fail to disclose your Social Security number, you may be reported to the Franchise Tax Board and be assessed a penalty of $100.

Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure by the Information Practices Act, including Civil Code section 1798.40. The Board makes every effort to protect the personal information you provide us; however, it may be disclosed in response to a Public Records Act request as allowed by the Information Practices Act, to another government agency as required by state or federal law or Civil Code section 1798.24; or in response to a court or administrative order, a subpoena, or a search warrant. Your name and address listed on this application will be disclosed to the public upon request if and when you become licensed. INFORMATION COLLECTION AND ACCESS The information requested herein is mandatory and is maintained by the Dental Board of California, 2005 Evergreen Street, Suite 1550, Sacramento, CA 92815, Executive Officer, 916-263-2300, in accordance with Business & Professions Code, §1600 et seq. Except for Social Security numbers, the information requested will be used to determine eligibility. Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Disclosure of your Social Security number is mandatory and collection is authorized by §30 of the Business & Professions Code and Pub. L 94-455 (42 U.S.C.A. §405(c)(2)(C)). Your Social Security number will be used exclusively for tax enforcement purposes, for compliance with any judgment or order for family support in accordance with Section 17520 of the Family Code, or for verification of licensure or examination status by a licensing or examination board, and where licensing is reciprocal with the requesting state. If you fail to disclose your Social Security number, you may be reported to the Franchise Tax Board and be assessed a penalty of $100. Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure. Your name and address listed on this application will be disclosed to the public upon request if and when you become licensed.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DENTAL BOARD OF CALIFORNIA
2005 Evergreen St., Suite 1550, Sacramento, CA 95815
P (916) 263-2300 | F (916) 263-2140 | www.dbc.ca.gov

CERTIFICATION OF PEDIATRIC MINIMAL SEDATION TRAINING

Notice to Applicants

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 Business and Professions Code 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. 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.

(APPLICANT TO COMPLETE QUESTIONS 1-3 AND EDUCATIONAL INSTITUTION TO COMPLETE QUESTION 4)

1. LEGAL NAME: LAST FIRST MIDDLE

2. LICENSE NUMBER:

3. NAME OF SCHOOL/EDUCATIONAL INSTITUTION

4. MINIMAL SEDATION TRAINING VERIFICATION:

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

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

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

☐ A COMMISSION ON DENTAL ACCREDITATION (CODA) RESIDENCY IN PEDIATRIC DENTISTRY.

I HEREBY CERTIFY THAT THE INFORMATION PROVIDED IN THIS SECTION OF THE FORM IS TRUE AND CORRECT AND CONFIRM THAT, ACCORDING TO THIS INSTITUTION'S RECORDS, _____ (NAME OF APPLICANT) SATISFACTORILY COMPLETED THE ABOVE REFERENCED TRAINING AT _____ (NAME OF INSTITUTION). THIS STUDENT WAS ENROLLED IN A _____ (NAME OF EDUCATIONAL PROGRAM) PROGRAM WHEN OBTAINING MODERATE SEDATION TRAINING ON THE FOLLOWING DATES: _____

EDUCATIONAL PROGRAM SEAL (IF APPLICABLE)

_____
SIGNATURE DATE

_____
PRINTED NAME/TITLE TELEPHONE

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DENTAL BOARD OF CALIFORNIA
2005 Evergreen St., Suite 1550, Sacramento, CA 95815
P (916) 263-2300 | F (916) 263-2140 | www.dbc.ca.gov

APPLICATION FOR USE OF ORAL CONSCIOUS SEDATION ON ADULT PATIENTS

FEES Application Fee: $459.00 (Must be enclosed with application) **APPLICATION FEES ARE NON-REFUNDABLE**	*For Office Use Only* Rec # _____ Fee Pd _____ Date Cashiered _____ Entity# _____ File # _____	*For Office Use Only* Date Received

*This application must be completed in its entirety or the application may be rejected as incomplete. Attach additional sheets if necessary.
* Any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit.
* Under Business and Professions Code (BPC) sections 31 and 494.5, the ~~State Board of Equalization (BOE~~)California Department of Tax and Fee Administration (CDTFA)~~-~~and the Franchise Tax Board (FTB) may share taxpayer information with the Board. You are required to pay your state tax obligation. This application may be denied or your permit may be suspended if you have a state tax obligation and the state tax obligation is not paid and your name appears on ~~either~~ the ~~BOE~~State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

(PLEASE PRINT CLEARLY OR TYPE)

1. SSN/ITIN:	2. BIRTH DATE (MM/DD/YYYY):
3. LEGAL NAME: LAST FIRST MIDDLE	
4. MAILING ADDRESS (ADDRESS OF RECORD – MAY BE A P.O. BOX):	
5. PRIMARY PRACTICE LOCATION (PHYSICAL ADDRESS):	
6. EMAIL ADDRESS (OPTIONAL):	
7. TELEPHONE NUMBER:	
8. FAX NUMBER (OPTIONAL)	

9. DENTAL LICENSE NUMBER:

10. **QUALIFICATION** – INDICATE UNDER WHICH METHOD LISTED BELOW YOU QUALIFY FOR AN ORAL CONSCIOUS SEDATION CERTIFICATE FOR ADULTS AND ATTACH APPROPRIATE DOCUMENTATION AS SET FORTH BELOW.

☐ SUCCESSFUL COMPLETION OF A POSTGRADUATE PROGRAM IN ORAL AND MAXILLOFACIAL SURGERY APPROVED BY THE COMMISSION ON DENTAL ACCREDITATION OR A COMPARABLE ORGANIZATION APPROVED BY THE BOARD AS PROVIDED IN TITLE 16, CALIFORNIA CODE OF REGULATIONS (CCR) SECTION 1044.2. APPLICANT MUST PROVIDE A COPY OF HIS OR HER DIPLOMA.

☐ SUCCESSFUL COMPLETION OF A PERIODONTICS OR GENERAL PRACTICE RESIDENCY OR ADVANCED EDUCATION IN A GENERAL DENTISTRY POST-DOCTORAL PROGRAM ACCREDITED BY THE COMMISSION ON DENTAL ACCREDITATION THAT MEETS THE DIDACTIC AND CLINICAL REQUIREMENTS OF CCR SECTION 1044.3. APPLICANT MUST PROVIDE A COPY OF HIS OR HER DIPLOMA.

☐ SUCCESSFUL COMPLETION OF A BOARD-APPROVED EDUCATIONAL PROGRAM ON ORAL MEDICATIONS AND SEDATION MEETING THE REQUIREMENTS IN CCR SECTION 1044.3.

☐ DOCUMENTATION OF 10 SUCCESSFUL CASES OF ORAL CONSCIOUS SEDATION PERFORMED BY THE APPLICANT ON ADULT PATIENTS IN ANY THREE-YEAR PERIOD ENDING NO LATER THAN DECEMBER 31, 2005 AS PROVIDED IN BPC SECTION 1647.20(d)). ATTACH FORM OCS-4 WITH COPY OF TREATMENT RECORDS.

~~10~~11. ARE YOU SERVING IN, OR HAVE YOU PREVIOUSLY SERVED IN, THE U.S. MILITARY?	YES ☐ NO ☐
~~11~~12. ARE YOU REQUESTING EXPEDITING OF THIS APPLICATION FOR HONORABLY DISCHARGED MEMBERS OF THE U.S. ARMED FORCES? *MILITARY HONORABLE DISCHARGE REQUIREMENTS* NOTE: PLEASESCAN AND ATTACH A COPY OF THE FOLLOWING DOCUMENTATION: CERTIFICATE OF RELEASE OR DISCHARGE FROM ACTIVE DUTY (DD-214), OR OTHER DOCUMENTARY EVIDENCE SHOWING DATE AND HONORABLE DISCHARGE TO RECEIVE EXPEDITED REVIEW.	YES ☐ NO ☐
~~12~~13. DO YOU ALREADY HOLD A VALID LICENSE, OR COMPARABLE AUTHORITY, TO PRACTICE DENTISTRY IN ANOTHER U.S. STATE OR TERRITORY, AND YOUR SPOUSE OR DOMESTIC PARTNER IS AN ACTIVE DUTY MEMBER OF THE ARMED FORCES OF THE UNITED STATES AND WAS ASSIGNED TO A DUTY STATION IN CALIFORNIA UNDER OFFICIAL ORDERS? IF YES, YOUR APPLICATION WILL RECEIVE AN EXPEDITED REVIEW. *MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENTS* NOTE: IF YOU MEET THE MILITARY SPOUSE OR DOMESTIC PARTNER REQUIREMENT PLEASE SCAN AND ATTACH THE FOLLOWING DOCUMENTATION TO THIS APPLICATION: • 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 • A COPY OF YOUR CURRENT DENTAL LICENSE IN ANOTHER STATE, DISTRICT, OR TERRITORY OF THE UNITED STATES. • A COPY OF THE MILITARY ORDERS ESTABLISHING YOUR SPOUSE OR PARTNER'S DUTY STATION IN CALIFORNIA	YES ☐ NO ☐

~~13~~14. DO ANY OF THE FOLLOWING STATEMENTS APPLY TO YOU: • YOU WERE ADMITTED TO THE UNITED STATES AS A REFUGEE PURSUANT TO SECTION 1157 OF TITLE 8 OF THE UNITED STATES CODE. • YOU WERE 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, • YOU HAVE A SPECIAL IMMIGRANT VISA AND WERE 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]. IF YOU SELECTED YES, YOU MUST ATTACH EVIDENCE OF YOUR STATUS AS A REFUGEE, ASYLEE, OR SPECIAL IMMIGRANT VISA HOLDER AS PROVIDED BELOW. FAILURE TO DO SO MAY RESULT IN APPLICATION PROCESSING DELAYS. “EVIDENCE” SHALL INCLUDE: • 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” • 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 THATTHE APPLICANT QUALIFIES FOR EXPEDITED LICENSURE PER BUSINESS AND PROFESSIONS CODE SECTION 135.4.	YES ☐ NO ☐

FACILITIES AND EQUIPMENT REQUIREMENTS - ALL EQUIPMENT SHOULD BE MAINTAINED, TESTED, AND INSPECTED ACCORDING TO THE MANUFACTURERS' SPECIFICATIONS.	
~~14~~15. DOES THE FACILITY HAVE 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?	YES ☐ NO ☐
~~15~~16. DOES THE FACILITY HAVE 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?	YES ☐ NO ☐
~~16~~17. DOES THE FACILITY HAVE A LIGHTING SYSTEM WHICH 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 WHICH MAYBE UNDERWAY AT THE TIME OF A GENERAL POWER FAILURE?	YES ☐ NO ☐
~~17~~18. DOES THE FACILITY HAVE 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?	YES ☐ NO ☐
~~18~~19. A. DOES THE FACILITY HAVE 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? B. IS ALL EQUIPMENT AT THE FACILITY AGE-APPROPRIATE AND CAPABLE OF ACCOMMODATING THE PATIENTS BEING SEEN AT THE PERMIT-HOLDER'S OFFICE?	YES ☐ NO ☐ YES ☐ NO ☐
~~19~~20. A. DOES THE FACILITY HAVE INHALATION SEDATION EQUIPMENT, AND IF USED IN CONJUNCTION WITH ORAL SEDATION, DOES IT HAVE 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 HAVE A FAIL-SAFE SYSTEM? B. IF THE ANSWER ABOVE IS YES, IS THE EQUIPMENT MAINTAINED AND CHECKED FOR ACCURACY AT LEAST ANNUALLY?	YES ☐ NO ☐ YES ☐ NO ☐
~~20~~21. DO YOU HAVE ANCILLARY EQUIPMENT ~~AND IS ALL ANCILLARY EQUIPMENT AT THE FACILITY MAINTAINED IN GOOD OPERATING CONDITION~~? FOR THE PURPOSES OF THIS QUESTION, ANCILLARY EQUIPMENT" MUST INCLUDE ALL OF THE FOLLOWING: (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. (4) PULSE OXIMETER	YES ☐ NO ☐

RECORDS - DO YOU MAINTAIN THE FOLLOWING RECORDS?

~~21~~22. 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, PATIENT'S CONSERVATOR, OR THE INFORMED CONSENT OF A PERSON AUTHORIZED TO GIVE SUCH CONSENT FOR THE PATIENT.	YES ☐ NO ☐
~~22~~23. 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 OR 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.	YES ☐ NO ☐
~~23~~24. DO YOU MAINTAIN DOCUMENTATION SHOWING THAT ALL EMERGENCY EQUIPMENT AND DRUGS ARE CHECKED AND MAINTAINED ON A PRUDENT AND REGULARLY SCHEDULED BASIS?	YES ☐ NO ☐
~~24~~25. DO YOU HAVE AVAILABLE AND READILY ACCESSIBLE AN EMERGENCY KIT OR CART (A) 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. (B) EMERGENCY DRUGS OF THE FOLLOWING TYPES: • EPINEPHRINE • BRONCHODILATOR • APPROPRIATE DRUG ANTAGONIST • ANTIHISTAMINIC • ANTICHOLINERGIC • ANTICONVULSANT • OXYGEN • DEXTROSE OR OTHER ANTIHYPOGLYCEMIC	YES ☐ NO ☐

~~25~~26. PROVIDE THE ADDRESSES OF ALL LOCATIONS OF PRACTICE WHERE YOU ADMINISTER OR ORDER THE ADMINISTRATION OF ORAL CONSCIOUS SEDATION. ALL OFFICES SHALL MEET THE STANDARDS SET FORTH IN REGULATIONS ADOPTED BY THE BOARD AT TITLE 16, CALIFORNIA CODE OF REGULATIONS SECTION 1044.5.

_____

_____

_____

IF NECESSARY, CONTINUE ON THE BACK OF THIS PAGE.

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing information, including attachments, is true and correct.

_____

Date: Signature of Applicant

INFORMATION COLLECTION AND ACCESS: Except for the email address and fax number, the information requested herein is mandatory and is maintained by the Dental Board of California (Board), 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, Executive Officer, 916-263-2300, in accordance with Business and Professions Code (BPC)sections1600 et seq. The Board collects the personal information requested on the following form as authorized by BPC sections 27, 30, 31, 114.5, 115.4, 135.4, 480, 494.5, 1647.31, 1647.32, 1647.33, 1715, and Title 16, California Code of Regulations sections 1044.1 and 1044.5. The Board uses this information to identify and evaluate applicants for permit or licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Disclosure of your Social Security number is mandatory, and collection is authorized by sections 29.5, 30, 31, and 494.5 of the Business & Professions Code and Pub. L 94-455 (42 U.S.C.A. § 405(c)(2)(C)). Your Social Security number will be used exclusively for tax enforcement purposes, for compliance with any judgment or order for family support in accordance with Section 17520 of the Family Code, measurement of employment outcomes of students who participate in career technical education programs offered by the California Community Colleges as required by BPC section 30, or for verification of licensure or examination status by a licensing or examination board, and where licensing is reciprocal with the requesting state. If you fail to disclose your Social Security number, you may be reported to the Franchise Tax Board and be assessed a penalty of $100.

Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure by the Information Practices Act, including Civil Code section 1798.40. The Board makes every effort to protect the personal information you provide us; however, it may be disclosed in response to a Public Records Act request as allowed by the Information Practices Act, to another government agency as required by state or federal law or Civil Code section 1798.24; or in response to a court or administrative order, a subpoena, or a search warrant. Your name and address listed on this application will be disclosed to the public upon request if and when you become licensed.

PROPOSED DOCUMENTS

ADDED TO THE

RULEMAKING FILE

State of California Department of Consumer Affairs

DENTAL BOARD OF CALIFORNIA
1432 HOWE AVENUE, SUITE 85, SACRAMENTO, CA 95825-3241
TELEPHONE: (916) 263-2300
FAX: (916) 263-2140

[Adopt]

APPLICATION FOR ORAL CONSCIOUS SEDATION FOR MINORS CERTIFICATE

Sections 1647.10-1647.17 Business and Professions Code;
Title 16 California Code of Regulations Sections 1044 - 1044.5

Non Refundable **FEE: $200**
(must be enclosed with application)
Section 1021 Title 16 California Code of Regulations

Receipt No._____RC_____

Amount_____Initials_____

Certificate No_____

Issued_____

Name _____

Address of Record (Mail)
Street and Number _____

City _____ ZIP Code _____

Address of Practice if different
Street and Number _____

City _____ ZIP Code _____

Telephone number (____) _____

FAX number _____

Email address _____

Birthdate _____

Dental License Number _____

QUALIFICATION – Indicate under which method listed below you qualify for an oral conscious sedation certificate for minors and attach appropriate documentation.

☐ Successful completion of a postgraduate program in oral and maxillofacial surgery, pediatric dentistry, or periodontics approved by the Commission on Dental Accreditation or a comparable organization approved by the Board.

☐ Successful completion of a general practice residency or other advanced education in a general dentistry program approved by the Board.

☐ Successful completion of a Board-approved educational program on oral medications and sedation. Applicant must provide completed Form OCS-2 to document completion.

By initialing below and completing the application you are certifying that any location where you administer oral conscious sedation to minor patients meets the Board's requirements set forth in regulation and in this application.

FACILITIES AND EQUIPMENT

1. 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.

   Initial_____

2. 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 that provides a firm platform for the management of cardiopulmonary resuscitation.

   Initial_____

3. A lighting system that is adequate to permit evaluation of the 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.

   Initial_____

4. 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.

   Initial_____

5. A positive-pressure oxygen delivery system capable of delivering 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 capable of accommodating minor patients of all ages and sizes.

   Initial_____

6. Inhalation sedation equipment, if used in conjunction with oral sedation, must have the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate for a minor patient's size and have a fail-safe system. The equipment must be maintained and checked for accuracy at least annually.

   Initial_____

7. Ancillary equipment maintained in good operating condition, which must include all of the following:
   (a) Oral airways capable of accommodating minor patients of all ages and sizes.
   (b) Sphygmomanometer with cuffs of appropriate size for minor patients of all ages and sizes.
   (c) Precordial/pretracheal stethoscope.
   (d) Pulse oximeter.

   Initial_____

RECORDS

1. Adequate medical history and physical evaluation records updated prior to each administration of oral conscious sedation that show at a minimum:
   (a) Name, age, sex and weight.
   (b) ASA Risk Assessment (American Society of Anesthesiologists Classification)
   (c) Rationale for sedation of the minor patient

   Initial_____

2. Oral Conscious Sedation records which show:
   (a) 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.
   (b) Intermittent quantitative monitoring of oxygen saturation, heart and respiratory rates and blood pressure as appropriate for specific techniques.
   (c) Drugs administered, amounts administered and time or times administered, including local and inhalation anesthetics.
   (d) Length of the procedure.
   (e) Any complication of oral sedation.
   (f) Statement of patient's condition at the time of discharge.

   Initial_____

3. Written informed consent of the parent or guardian.

   Initial_____

EMERGENCY CART OR KIT

1. Equipment and drugs appropriate for the age and size of the patients to resuscitate a non breathing and unconscious minor patient and provide continuous support while the patient is transported to a medical facility.
2. Vasopressor
3. Corticosteroid
4. Bronchodilator
5. Appropriate drug antagonists
6. Antihistaminic
7. Anticholinergic
8. Anticonvulsant
9. Oxygen
10. Dextrose or other antihypoglycemic
11. Documentation that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis.

Initial_____

EMERGENCIES All persons directly involved with the care of minor patients must be certified in basic cardiac life support (CPR) and recertified biennially.

Initial_____

Pursuant to Business and Professions Code 1647.14(b), a dentist who administers, or who orders the administration of oral conscious sedation for a minor patient shall be physically present in the treatment facility while the patient is sedated and shall be present until discharge of the patient from the facility.

Initial_____

Provide the addresses of all locations of practice where you order or administer oral conscious sedation to minor patients. All offices must meet the standards set forth by the Dental Board of California in regulations adopted by the Board.

_____

_____

_____

_____

IF NECESSARY, CONTINUE ON BACK OF THIS PAGE.

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing is true and correct and I hereby request a certificate to administer or order the administration of oral conscious sedation of minors in my office setting(s) as specified by the Dental Practice Act and regulations adopted by the Board. Falsification or misrepresentation of any item or response on this application or any attachment hereto is sufficient basis for denying or revoking this certificate.

_____

Signature of Applicant

INFORMATION COLLECTION AND ACCESS

The information requested herein is mandatory and is maintained by Dental Board of California, 1432 Howe Ave, Suite 85, Sacramento, CA 95825, Executive Officer, 916-263-2300, in accordance with Business & Professions Code, §1600 et seq. Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure. Applicants are advised that the names(s) and address(es) submitted may, under limited circumstances, be made public.

State of California Department of Consumer Affairs

DENTAL BOARD OF CALIFORNIA
1432 HOWE AVENUE, SUITE 85, SACRAMENTO, CA 95825-3241
TELEPHONE: (916) 263-2300
FAX: (916) 263-2140

[REPEAL]

APPLICATION FOR ADULT ORAL CONSCIOUS SEDATION CERTIFICATE

Sections 1647.18-1647.26 Business and Professions Code;

Non Refundable **FEE: $200**
(must be enclosed with application)
Section 1021 Title 16 California Code of Regulations

Receipt No._____ RC_____
Amount_____ Initials_____
Certificate No_____
Issued_____

Name _____

Address of Record (Mail)
Street and Number _____

City _____ ZIP Code _____

Address of Practice if different
Street and Number _____

City _____ ZIP Code _____

Telephone number ( )_____ FAX _____

Email address _____

Birthdate _____ Dental License Number _____

QUALIFICATION – Indicate under which method listed below you qualify for an oral conscious sedation certificate for adults and attach appropriate documentation.

☐ Successful completion of a postgraduate program in oral and maxillofacial surgery approved by the Commission on Dental Accreditation or a comparable organization approved by the Board. Applicant must provide a copy of his or her diploma.

☐ Successful completion of a periodontics or general practice residency or advanced education in a general dentistry post-doctoral program accredited by the Commission on Dental Accreditation that meets the didactic and clinical requirements of Section 1044.3 of the Business and Professions Code. Applicant must provide a copy of his or her diploma.

☐ Successful completion of a Board-approved educational program on oral medications and sedation. Applicant must provide a copy of his or her certificate of completion.

☐ Documentation of 10 successful cases 1647.20(d). Attach Form OCS-4 with copy of treatment records.

Pursuant to Business and Professions Code 1647.22(b), a dentist who administers, or who orders the administration of oral conscious sedation for an adult patient shall be physically present in the treatment facility while the patient is sedated and shall be present until discharge of the patient from the facility.

Provide the addresses of all locations of practice where you order or administer oral conscious sedation to adult patients.

_____

_____

_____

_____

IF NECESSARY, CONTINUE ON BACK OF THIS PAGE.

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing is true and correct and I hereby request a certificate to administer or order the administration of adult oral conscious sedation in my office setting(s) as specified by the Dental Practice Act. I understand that falsification or misrepresentation of any item or response on this application or any attachment is grounds for denying my application for a certificate.

_____

Signature of Applicant

INFORMATION COLLECTION AND ACCESS

The information requested herein is mandatory and is maintained by Dental Board of California, 1432 Howe Ave, Suite 85, Sacramento, CA 95825, Executive Officer, in accordance with Business & Professions Code, §1600 et seq. Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure. Applicants are advised that the names(s) and address(es) submitted will be release to the public upon request and may be posted on the Internet.

State of California Department of Consumer Affairs

DENTAL BOARD OF CALIFORNIA
1432 HOWE AVENUE, SUITE 85, SACRAMENTO, CA 95825-3241
TELEPHONE: (916) 263-2300
FAX: (916) 263-2140

[Adopt]

DOCUMENTATION OF ADULT ORAL CONSCIOUS SEDATION CASES

An applicant for an Oral Conscious Sedation Certificate may document ten cases of oral conscious sedation of patients 13 years or older performed by the applicant in any three-year period ending no later than December 31, 2005. To document, complete this form summarizing the ten cases, and attach legible copies of records of pre-operative evaluation, medical history, monitoring of vital signs throughout the procedure, and condition at discharge. Redact all personal information on the records, and number them as cases 1-10. Submit these documents with the application (Form OCS-3 Rev 03/07). **(Print or Type)**

Name of Applicant _____ Dental License _____

CASE 1 - _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed _____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____

Patient's condition at discharge _____

CASE 2 – _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed _____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____

Patient's condition at discharge _____

CASE 3 - _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed _____ Duration of Sedation _____
Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____

Patient's condition at discharge _____

--Attach legible copies of required records to completed form--

CASE 4 – _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed_____ Duration of Sedation _____

Briefly describe method, amount, and specific oral conscious sedation agent administered_____

_____

_____

_____

How was the patient monitored and by whom?_____

Patient's condition at discharge_____

CASE 5 – _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed_____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered_____

_____

_____

_____

How was the patient monitored and by whom?_____

Patient's condition at discharge_____

CASE 6 – _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed_____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered_____

_____

_____

_____

How was the patient monitored and by whom?_____

Patient's condition at discharge_____

CASE 7 – _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed_____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

_____

_____

How was the patient monitored and by whom?_____

Patient's condition at discharge_____

--Attach legible copies of required records to completed form--

CASE 8 – _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed_____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

_____

_____

_____

How was the patient monitored and by whom?_____

Patient's condition at discharge_____

CASE 9 – _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed_____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

_____

_____

_____

How was the patient monitored and by whom?_____

Patient's condition at discharge_____

CASE 10 - _____
Patient Sex Patient Age Patient Weight Date of Procedure

Type of Procedure Performed_____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

_____

_____

_____

How was the patient monitored and by whom?_____

Patient's condition at discharge_____

--Attach legible copies of required records to completed form--

Certification – I certify under the penalty of perjury under the laws of the State of California that the information provided in and attached to this form is true and accurate.

_____
Signature of Applicant Date

Addendum to Initial Statement of Reasons

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

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

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

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

separately for each permit.

Nothing in this section shall limit or restrict the application of Section 35782.

CHAPTER 884

An act to add Section 12811.1 to, the Vehicle Code, relating to licenses.

[Approved by Governor September 21, 1979. Filed with Secretary of State September 22, 1979.]

The people of the State of California do enact as follows:

SECTION 1. Section 12811.1 is added to the Vehicle Code, to read:

12811.1. (a) Upon the applicant's request, the department shall issue an adhesive backed medical information card which contains a format permitting the licensee to specify blood type, allergies, past or present medical problems, any medication being taken, the name of the licensee's doctor, the person to notify in case of an emergency, and whether the licensee is under a doctor's care.

(b) The medical information card, which shall be a different color than the anatomical gift sticker authorized by Section 12811, shall be the same size as a driver's license and shall be designed to be affixed to the reverse side of the license.

This section shall become operative on January 1, 1981.

SEC. 2. The Department of Motor Vehicles' cost in issuing the medical information card shall be included in the department's budget commencing with the budget for the 1980–81 fiscal year and shall be appropriated from the General Fund.

CHAPTER 885

An act making an appropriation to the Office of Statewide Health Planning and Development, relating to health personnel training programs.

[Approved by Governor September 21, 1979. Filed with Secretary of State September 22, 1979.]

The people of the State of California do enact as follows:

SECTION 1. The sum of three million one hundred eight thousand four hundred fifty dollars ($3,108,450) is hereby appropriated from the General Fund to the Office of Statewide Health Planning and Development for expenditure during the

1980–81, 1981–82, 1982–83, and 1983–84 fiscal years in accordance with the following schedule:

Schedule

(a) For contracts with accredited medical schools, with programs which train primary care physician's assistants, with programs which train primary care nurse practitioners, and with hospitals or other health care delivery systems located in California, which meet the standards of the Health Manpower Policy Commission established pursuant to Chapter 1 (commencing with Section 69270) of Part 42 of Division 5 of Title 3 of the Education Code $3,002,450

(b) For the period from July 1, 1980, to September 30, 1984, for insuring proper administration and evaluation of training contracted for pursuant to Chapter 1 (commencing with Section 69270) of Part 42 of Division 5 of Title 3 of the Education Code $106,000

CHAPTER 886

An act to add Article 2.7 (commencing with Section 1646) to Chapter 4 of Division 2 of the Business and Professions Code, relating to dentistry, and making an appropriation therefor.

[Approved by Governor September 21, 1979. Filed with Secretary of State September 22, 1979.]

The people of the State of California do enact as follows:

SECTION 1. Article 2.7 (commencing with Section 1646) is added to Chapter 4 of Division 2 of the Business and Professions Code, to read:

Article 2.7. Use of General Anesthesia

1646. (a) General anesthesia, as used in this article, consists of the use of any drug, element, or other material which results in the elimination of all sensations accompanied by a state of unconsciousness.

(b) The conscious patient, as opposed to the patient in an unconscious state, is defined, for purposes of this article, as one with intact protective reflexes, including the ability to maintain an airway and who is capable of rational response to question or command.

1646.1. No dentist shall administer or directly supervise the administration of general anesthesia on an outpatient basis for dental patients unless such dentist possesses a permit of authorization issued by the board. The dentist holding such permit shall be subject to review by the board and such permit shall be renewed annually.

This article shall not apply to the administration of local anesthesia or to conscious-patient sedation.

The Joint Commission 70-year Historical Timeline

1950s

1950-51
– The American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association join with the ACS as corporate members to create the Joint Commission on Accreditation of Hospitals (JCAH), an independent, not-for-profit organization, whose primary purpose is to provide voluntary accreditation.

1952
– Edwin L. Crosby, M.D., becomes the first director

1953-1959
– JCAH publishes Standards for Hospital Accreditation.
– Kenneth Babcock, M.D., becomes director of JCAH.

1960s

1965
– Congress passes the Social Security Amendments of 1965 with a provision that hospitals accredited by JCAH are "deemed" to be in compliance and, thus, able to participate in the Medicare and Medicaid programs.

1970s

1970
– The Accreditation Council for Psychiatric Facilities is established and accreditation for psychiatric facilities, substance abuse programs and community mental health programs begins.

1975-77
– The Accreditation Council for Ambulatory Health Care is established and accreditation for ambulatory health care facilities begins.

1978-79
– JCAH establishes an agreement with the College of American Pathologists to recognize CAP accreditation of a laboratory in a JCAH-accredited hospital in lieu of the Commission's accreditation of the laboratory.

1980s

1982-83
– Accreditation for hospice care organizations begins.

1986
– Quality Healthcare Resources® (QHR), Inc. is formed as a not-for-profit consulting subsidiary of JCAH. (QHR later becomes Joint Commission Resources.)

1987-1989
– The organization name changes to the Joint Commission on Accreditation of Healthcare Organizations to reflect an expanded scope of activities.

1990s

1994
– Quality Healthcare Resources, Inc.® and the Joint Commission form Joint Commission International.

1995
– The federal government recognizes Joint Commission laboratory accreditation services.

1999
– The Joint Commission establishes a toll free hot line to encourage patients, their families, caregivers, and others to share concerns regarding quality of care issues at accredited health care organizations.

2000s

2000
– Joint Commission International publishes the first comprehensive set of international quality standards for hospitals

2001
– A new accreditation program for office-based surgery practices is introduced.
– A new accreditation program for critical access hospitals is launched.

2002
– The Disease-Specific Care Certification program launches.

2003
– The Joint Commission creates The Gold Seal of Approval® that is displayed on all certificates of accreditation.

2006
– The Joint Commission begins conducting on-site accreditation surveys and certification reviews on an unannounced basis.

2007
– The Joint Commission on Accreditation of Healthcare Organizations shortens its name to The Joint Commission.

2009
– The Joint Commission launches its Center for Transforming Healthcare.

2010s

2010
– The Centers for Medicare and Medicaid Services names The Joint Commission a designated accreditor of advanced diagnostic imaging centers.

2012
– The Joint Commission and the American Heart Association /American Stroke Association announce the launch of the Disease-Specific Care Advanced Certification Program for Comprehensive Stroke Centers.

2013
– The Joint Commission debuts its new Nursing and Rehabilitation Center Accreditation program, and for the first time offers a Rehabilitation and Advanced Care Certification option.

2016
– Advanced Certification for Total Hip and Total Knee Replacement launched for hospitals, critical access hospitals and ambulatory surgery centers.

2017
– Comprehensive Cardiac Center Certification was introduced to recognize hospitals that demonstrate excellence in cardiac care.

2018
– The American Academy of Orthopaedic Surgeons and The Joint Commission announce a collaboration to incorporate AAOS clinical expertise into standards development and performance measurement requirements for Total Hip and Knee Replacement Certification.

2019
– Joint Commission Resources introduced its Tracers with AMP Analytics Reporting Tool, a cloud-based software platform that helps organizations assess quality of care, levels of compliance, and identify areas of vulnerability in their organizations.

2020
– The Joint Commission issued a statement supporting the use of standard face masks and/or respirators provided from home when health care organizations cannot provide access to protective equipment that is commensurate with the risk health care workers are exposed to amid the COVID -19 pandemic.

Present

The Joint Commission