STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
DENTAL BOARD OF CALIFORNIA
2005 Evergreen Street, Suite 1550, Sacramento, CA 95815
P (916) 263-2300 F (916) 263-2140 www.dbc.ca.gov

NOTICE OF PUBLIC MEETING – Notice is hereby given that a public meeting of the Dental Board of California will be held as follows:

Thursday, November 4, 2010

Embassy Suites LAX/South
1440 E. Imperial Avenue
El Segundo, CA 90245
1-310-640-3600

*Public comments will be taken on agenda items at the time the specific item is raised. The Board may take action on any item listed on the agenda, unless listed as informational only. All times are approximate and subject to change. Agenda items may be taken out of order to accommodate speakers and to maintain a quorum. The meeting may be cancelled without notice. Time limitations for discussion and comment will be determined by the President. For verification of the meeting, call (916) 263-2300 or access the Board's Web Site at **www.dbc.ca.gov**. This Board meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Richard DeCuir, Executive Officer at 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, or by phone at (916) 263-2300. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation*

Thursday, November 4, 2010

8:00 AM DENTAL BOARD OF CALIFORNIA – FULL BOARD
Open Session

ROLL CALL.....Establishment of a Quorum

COMMITTEE MEETINGS – SEE ATTACHED AGENDAS

- EXAMINATION COMMITTEE
  See attached Examination Committee agenda
- DENTAL ASSISTING COMMITTEE
  See attached Dental Assisting Committee agenda
- LICENSING, CERTIFICATION, AND PERMITS COMMITTEE
  See attached Licensing, Certification, and Permits Committee agenda
- ENFORCEMENT COMMITTEE
  See attached Enforcement Committee agenda
- LEGISLATIVE AND REGULATORY COMMITTEE
  See attached Legislative and Regulatory Committee agenda

LUNCH BREAK estimated to occur between Noon and 12:30 – The break will be for one hour.

AGENDA ITEM 1.....Department of Consumer Affairs (DCA) Director's Report

AGENDA ITEM 2.....Update on Federal Healthcare Reform Legislation

AGENDA ITEM 3.....Update Regarding Dental Board of California's Sunset Review

AGENDA ITEM 4.....Discussion and Possible Action to Consider:
(A) Comments Received During the 45-Day Comment Period Relative to Amendments to Title 16, CCR, Section 1005 for the Minimum Standards for Infection Control, and

(B) Adoption of Amendments to Title 16, CCR, Section 1005 for the Minimum Standards for Infection Control

AGENDA ITEM 5.....Discussion and Possible Action to Consider:
(A) Comments Received During the 15-Day Modified Text Notice Comment Period Relative to Amendments to Title 16, CCR, Sections 1070, 1070.1, 1070.2, 1071, and Proposed Additions to Title 16, CCR, Section 1070.6, 1070.7, 1070.8 for Dental Assisting Educational Programs and Courses, and

(B) Adoption of Amendments to Title 16, CCR, Sections 1070, 1070.1, 1070.2, 1071, and Proposed Additions to Title 16, CCR, Section 1070.6, 1070.7, 1070.8 for Dental Assisting Educational Programs and Courses

AGENDA ITEM 6.....Request by the California Dental Association Relating to Review and Possible Amendments to Title 16, California Code of Regulations (CCR) Section 1049 Relative to Mobile Dental Clinics

AGENDA ITEM 7.....Future Meeting Dates for Board Meetings

PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA
Note: The Board may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except whether to decide to place the matter on the agenda of a future meeting. (Government Code Section 11125 and 11125.7(a))

***CLOSED SESSION - DISCIPLINARY MATTERS AND LITIGATION**

(a) Deliberate and Take Action on Disciplinary Matters
*The Board will meet in closed session as authorized by Government Code Section 11126(c)(3).

(b) Receive Advice from Counsel on Litigation
Michael L. Potts et al. v. Brian Stiger et al. No. 2:03-CV-00348-JAM DAD, US District Court, Eastern District of Columbia
*The Board will meet in closed session as authorized by Government Code Section 11126(e).

RETURN TO OPEN SESSION

PUBLIC COMMENT

RECESS

STATE OF CALIFORNIA
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MEMORANDUM

DATE	November 4, 2010
TO	Dental Board Members
FROM	Karen Fischer, Administrative Analyst Dental Board of California
SUBJECT	**Agenda Item 1:** Department of Consumer Affairs (DCA) Director's Report

A representative from the Executive Office of the Department of Consumer Affairs will attend the Dental Board meeting and will give the Director's Report.

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MEMORANDUM

DATE	November 4, 2010
TO	Dental Board Members
FROM	Karen Fischer, Administrative Analyst Dental Board of California
SUBJECT	**Agenda Item 2:** Update on Federal Healthcare Reform Legislation

A representative from the Department of Consumer Affairs' Directors Office will give a verbal report.

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MEMORANDUM

DATE	November 4, 2010
TO	Dental Board Members Dental Board of California
FROM	Richard DeCuir, Executive Officer Dental Board of California
SUBJECT	**Agenda Item 3** – Update on Sunset Review

Richard DeCuir, Executive Officer of the Dental Board of California will give a verbal report.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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MEMORANDUM

DATE	October 27, 2010
TO	Dental Board Members Dental Board of California
FROM	Sarah Wallace Legislative & Regulatory Analyst
SUBJECT	**Agenda Item 4(A):** Discussion and Possible Action to Consider Comments Received During the 45-Day Comment Period Relative to Amendments to Title 16, CCR Section 1005 for the Minimum Standards for Infection Control

Background:
At the July 26, 2010 meeting, the Board accepted proposed regulatory amendments to the California Code of Regulations, Title 16, Section 1005 relative to the minimum standards for infection control. The Board directed staff to notice the text for the 45-day comment period and set a regulatory hearing.

The proposed regulatory amendments were mailed to interested parties and posted on the Board's web site on August 26, 2010. The 45-day public comment period began on August 27, 2010 and ended on October 11, 2010. The regulatory hearing was held on October 11, 2010. Comments were received from:

- Dr. Earl Johnson,
- California Dental Association,
- Dental Assisting Alliance,
- Dental Hygiene Committee of California,
- California Association of Dental Assisting Teachers, and
- OSHA Review Incorporated

Staff has included a recommended response to each comment.

Board Action Requested
The Board may take action to reject or accept any comments. A rationale must be provided for any comments that are rejected. If comments are accepted, and the regulatory language is modified, the modified text must be noticed for a 15-day public comment period, and any negative comments received during that time must be brought back to the Board for a response.

STAFF RECOMMENDATIONS FOR RESPONSE TO COMMENTS RECEIVED DURING THE 45-DAY PUBLIC COMMENT PERIOD FOR MINIMUM STANDARDS FOR INFECTION CONTROL, CALIFORNIA CODE OF REGULATIONS, 1005

COMMENTS RECEIVED FROM THE DENTAL HYGIENE COMMITTEE OF CALIFORNIA

The Dental Hygiene Committee provided the following suggested modified text:

Sterilization and Disinfection:

~~(9)~~(10) ~~Heat stable c~~Critical ~~and semi-critical~~ instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include ~~shall be cleaned and sterilized before use by using~~ steam under pressure (autoclaving), ~~dry heat, or~~ chemical (formaldehyde) vapor, and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. ~~in the form of package or being wrapped before sterilization if they are not to be used immediately after being sterilized.~~ These instruments, items, and devices, shall remain sealed and stored in a manner so as to prevent contamination. ~~FDA cleared chemical sterilants/disinfectants shall be used for sterilization of heat sensitive critical items and for high level disinfection of heat sensitive semi-critical items.~~

~~(10)~~(11) ~~Critical and s~~Semi-critical ~~instruments or containers of critical and semi-critical instruments~~ items shall be pre-cleaned, packaged or wrapped and sterilized after each use. ~~by a heat or vapor m~~Methods of sterilization include steam under pressure, chemical vapor and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection and packaged or wrapped upon completion of the disinfection process. ~~Shall be packaged or wrapped in the form of package or being wrapped before sterilization. Before sterilization if they are not to be used immediately after being sterilized.~~ These packages or containers shall remain sealed ~~unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used~~ and shall be stored in a manner so as to prevent contamination.

Staff recommends acceptance of this suggested modified text.

COMMENTS RECEIVED FROM DR. EARL JOHNSON

Dr. Earl Johnson provided the following comment:

Sterilization and Disinfection : Paragraph ~~(9)~~(10)

This paragraph mandated that heat sensitive items must be processed **with high level disinfection in the form of (a) package or being wrapped before sterilization.**

Please be aware that the conventional method of high level disinfecition used for heat sensitive surgical instruments is complete submersion in a disinfectant for up to 12 hours.

Wrapping or packaging an item before submersion will do three things:

1. Severely restrict the disinfectant's ability to contact the contaminated instrument.
2. Reduce the reliability of the disinfection process.
3. Create a very wet package that cannot be dried easily before storage and its ultimate use.

Proposal: Edit this regulatory text as follows:

If a critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection **and stored** in ~~the form of~~ a **wrapped** package or **cassette** ~~being wrapped before sterilization~~ if ~~they are~~ **it is** not to be used immediately after being sterilized.

Advantages:

1. The disinfection process will be unimpeded by the packaging/wrapping medium.
2. Consistent disinfection will be assured.
3. The disinfected items will be protected from re-contamination during storage.

Staff recommends rejection of this comment. The Dental Hygiene Committee's suggested modified text specifies that the disinfection process must be complete before packaging or wrapping.

COMMENTS RECEIVED FROM THE CALIFORNIA ASSOCIATION OF DENTAL ASSISTING TEACHERS

The California Association of Dental Assisting Teachers provided the following suggested modified text:

Sterilization and Disinfection:

~~(9)~~(10) ~~Heat stable c~~Critical ~~and semi-critical~~ instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include ~~shall be cleaned and sterilized before use by using~~ steam under pressure (autoclaving), ~~dry heat, or~~ chemical (formaldehyde) vapor, and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection ~~in the form of~~ and package or wrapped upon completion of the disinfection process. ~~being wrapped before sterilization if they are not to be used immediately after being sterilized.~~ These instruments, items, and devices, shall remain sealed and shall be stored in a manner so as to prevent contamination. ~~FDA cleared chemical sterilants/ disinfectants shall be used for sterilization of heat sensitive critical items and for high level disinfection of heat sensitive semi critical items.~~

~~(10)~~(11) ~~Critical and s~~Semi-critical instruments ~~instruments or containers of critical and semi critical instruments~~ items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. ~~by a heat or vapor m~~Methods of sterilization include steam under pressure (autoclaving), chemical vapor (formaldehyde) and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection and packaged or wrapped upon completion of the disinfection process. ~~shall be packaged or wrapped in the form of package or being wrapped before sterilization. before sterilization if they are not to be used immediately after being sterilized.~~ These instruments, items and devices ~~packages or containers~~ shall remain sealed ~~unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used~~ and shall be stored in a manner so as to prevent contamination.

Staff recommends rejection of this comment. The Dental Hygiene Committee's suggested modified text specifies that the disinfection process must be complete before packaging or wrapping. However, staff recommends utilizing some of CADAT's suggested modifications to 1005(b)(11) to provide consistency with the definition in section 1005(b)(10). The suggested modified text is as follows:

~~(10)~~(11) ~~Critical and s~~Semi-critical ~~instruments or containers of critical and semi-critical instruments~~ instruments, items, and devices shall be pre-cleaned, packaged or wrapped and sterilized after each use. ~~by a heat or vapor m~~Methods of sterilization include steam under pressure (autoclaving), chemical vapor (formaldehyde) and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection and packaged or wrapped upon completion of the disinfection process. ~~Shall be packaged or wrapped in the form of package or being wrapped before sterilization. Before sterilization if they are not to be used immediately after being sterilized.~~ These packages or containers shall remain sealed ~~unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used~~ and shall be stored in a manner so as to prevent contamination.

COMMENTS RECEIVED FROM THE DENTAL ASSISTING ALLIANCE

Comment 1:

The Dental Assisting Alliance provided the following comment:

> Subdivisions (b)(10) and (11) are incorrect, and therefore unclear.
>
> It is not appropriate or effective to wrap a heat-sensitive item before high-level disinfection or sterilization of the item, since the method of high level disinfection or sterilization for heat-sensitive items is by immersion in a liquid chemical sterilant/disinfectant.
>
> It is also inconsistent with CDC Guidelines to wrap instruments after high level disinfection or cold sterile processing. According to CDC Guidelines *"If stored before use, the instrument should not be considered sterile and should be sterilized again just before use".*
>
> Also, critical items must be sterilized with an FDA cleared chemical.
>
> Following is our suggested revised language for each of the subdivisions, without strikeout or underline:
>
> > (10) Critical instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include steam under pressure (autoclaving), chemical (formaldehyde) vapor, and dry heat. These instruments, items, and devices shall be packaged or wrapped before sterilization if they are not to be used immediately after sterilization and shall remain sealed until the day of use and stored in a manner so as to prevent contamination. If a critical item is heat sensitive, it shall, at minimum, be processed with an FDA cleared chemical sterilant to achieve sterilization, and if not used immediately, shall be re-processed immediately prior to use.
> >
> > (11) Semi-critical items shall be pre-cleaned, packaged or wrapped, and sterilized after each use. Methods of sterilization include steam under pressure, chemical vapor and dry heat. These instruments, items, and devices shall be packaged or wrapped before sterilization if they are not to be used immediately after sterilization and shall remain sealed until the day of use and stored in a manner so as to prevent contamination. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with an FDA cleared chemical steriliant/disinfectant to achieve high level disinfection.

Staff recommends rejection of this comment. The Dental Hygiene Committee's suggested modified text specifies that the disinfection process must be complete before packaging or wrapping.

COMMENTS RECEIVED FROM THE CALIFORNIA DENTAL ASSOCIATION

Comment 1:
The California Dental Association provided the following comment:

> 1005(a) (1) The new language in this paragraph uses the phrase "safe injection practices." CDA proposes revising the phrase to "safe handling of sharps" to broaden the focus from needles to all dental sharps.

Staff recommends acceptance of this comment.

Comment 2:
The California Dental Association provided the following comment:

> Section 1005 (a) (2) – Add "instruments" in second sentence to be consistent with the definition in Section 1005 (a) (3).
>
> The following language is suggested:
>
> "'Critical items' confer a high risk for infection if they are contaminated with any microorganism. These include all instruments, devices, and other items used to penetrate soft tissue or bone."

Staff recommends acceptance of this comment.

Comment 3:
The California Dental Association provided the following comment:

> Section 1005 (a) (5) – Delete "is the least effective disinfection process" as it is unnecessary. Neither the definition for intermediate-level disinfection nor the definition for high-level disinfection includes such a statement.
>
> The following language is suggested:
>
> "'Low-level disinfection' kills some bacteria, some viruses and fungi, but does not kill bacterial spores or mycobacterium tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals."

Staff recommends rejection of this comment. The current definition is necessary to specify the distinction between disinfection levels for infection control.

Comment 4:
The California Dental Association provided the following comment:

> Section 1005 (a) (8) – Remove "germicides must be used in accordance with intended use and label instructions" from the second sentence. Section (a) is Definition of terms, while Section (b) are practice standards. Because this sentence is a practice standard, it should be moved to Section 1005 (b).

Staff recommends acceptance of this comment.

Comment 5:
The California Dental Association provided the following comment:

> Section 1005 (a) (10) – Similar to #4 above, remove second and third sentences from Section 1005 (a) and move them to Section 1005 (b) because it is not part of the definition of "cleaning," but is a practice standard.

Staff recommends acceptance of this comment.

Comment 6:
The California Dental Association provided the following comment:

> Section 1005 (a) (11) – Remove the examples contained within the parenthesis "(shoes, gowns/labcoats)" as they are unnecessary. Additionally any mention of gowns/labcoats should be changed to "protective attire" to be consistent with Cal/OSHA's Bloodborne Pathogens Standard (Section 5193 Title 8 CCR).
>
> Proposed Section 1005 (a) (11) references "shoes" without qualification or limitation. This section could be interpreted as employers are required to provide shoes to employees. Cal/OSHA requires employers to pay for the PPE employees must don to perform their job safely. Shoes are specified by Cal/OSHA for only those situations where it is reasonable to expect "gross" contamination such as in autopsies and orthopedic surgery.
>
> Additionally, Section 1005 references both "gowns/labcoats" and "gowns", which creates confusion. Section 1005 (a) (11) uses the term "gowns/labcoats," while all other line items of this proposed regulation refer only to "gowns." It is unclear if those sections referring to "gowns" include "labcoats" or only "gowns."
>
> Clarity and consistency are needed.
>
> The following language is suggested:

"(11) "Personal Protective Equipment" (PPE) is specialized clothing or equipment worn or used for protection against a hazard. PPE items may include, but are not limited to, gloves, masks, respiratory devices, protective eyewear, and protective attire which are intended to prevent exposure to blood, body fluids, and OPIM, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants and shirts are not considered to be PPE."

Staff recommends acceptance of this comment.

Comment 7:

The California Dental Association provided the following comment:

1005 (a) (12) "Other Potentially Infectious Materials" (OPIM) is defined in this section, but the proposed language fails to cover hepatitis B and C. In addition, the HIV section is worded awkwardly. CDA suggests adopting Cal/OSHA's definition in the Bloodborne Pathogens Standard (Section 5193 Title 8 CCR).

§5193. Bloodborne Pathogens.
"Other Potentially Infectious Materials" means:

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response;
(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
(3) Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:
(A) Cell, tissue, or organ cultures from humans or experimental animals;
(B) Blood, organs, or other tissues from experimental animals; or
(C) Culture medium or other solutions.

Staff recommends partial acceptance of this comment. Staff recommends rejecting (1) of Cal/OSHA's definition of OPIM. The current definition is derived from Cal/OSHA's definition and is specific to the practice of dentistry. It is unnecessary to include the entire definition specified by Cal/OSHA. Staff recommends acceptance of using the proposed language regarding hepatitis B and C. Staff recommends replacing Section 1005(a)(12)(C) with the following:

~~(11)~~(12) "Other Potentially Infectious Materials" (OPIM) means any one of the following:

(A) H~~h~~uman body fluids such as saliva in dental procedures and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids~~;~~.

(B) Aany unfixed tissue or organ (other than intact skin) from a human (living or dead);.

(C) ~~Human Immunodeficiency Virus (HIV) -containing cell or tissue cultures, organ culture and blood, or other tissues from experimental animals~~ Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:

(i) Cell, tissue, or organ cultures from humans or experimental animals;
(ii) Blood, organs, or other tissues from experimental animals; or
(iii) Culture medium or other solutions..

Comment 8:

The California Dental Association provided the following comment:

> Section 1005 (b) – This section needs clarity. Section (b) requires compliance with Cal/OSHA requirements for infection control, specifically bloodborne pathogens and aerosol transmitted diseases. Section 3384 Title 8 CCR is also pertinent because it specifies PPE requirements during chemical handling. Additionally, the California Division of Occupational Safety and Health is referred to as Cal/OSHA, not "Cal-DOSH."
>
> The following language is suggested:
>
> "(b) All DHCP shall comply with and enforce the California Division of Occupational Safety and Health (Cal/OSHA) requirements for infection control, as applicable, and the following minimum precautions to prevent the transmission of pathogens in health care settings."

Staff recommends rejection of this comment. The suggested change is unnecessary and does not provide further clarity. However, staff does suggest modifying the language to correctly identify the California Division of Occupational Safety and Health as Cal/OSHA.

Comment 9:

The California Dental Association provided the following comment:

> Section 1005 (b) (4) – Clarify the PPE requirements for chemical handling. This section states that "puncture resistant utility gloves and other PPE shall be worn when handling hazardous chemicals." It is unclear as to what "other PPE" would be required under the new rules. CDA suggests "chemical-resistant utility gloves when handling hazardous chemicals, not "puncture resistant." "Other PPE" should be defined if that language remains.
>
> The following language is suggested:
>
> "(4) All DHCP shall wear surgical facemasks in combination with either chin length

plastic face shields or protective eyewear whenever there is potential for aerosol spray, splashing or spattering of the following: droplet nuclei, blood, OPIM, or chemical or germicidal agents. Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals. After each patient, masks shall be changed and disposed. After each patient treatment, face shields and protective eyewear shall be cleaned and disinfected, or disposed."

Staff recommends acceptance of this comment.

Comment 10:

The California Dental Association provided the following comment:

> Section 1005 (b) (5) – Change "gowns" to "protective attire" (see Item #6 above) and Cal-DOSH to Cal/OSHA (see Item #8 above). Additionally change "splattering" to "spattering" to be consistent with Section 1005 (b) (4).
>
> The following language is suggested:
>
> "(5) Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items. All DHCP shall wear reusable or disposable protective attire whenever there is a potential for aerosol spray, splashing or spattering of blood, OPIM, or chemicals and germicidal agents. Protective attire must be changed daily or between patients if it should become moist or visibly soiled. All PPE used during patient care shall be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with Cal/OSHA Bloodborne Pathogens Standards. (Title 8, California Code of Regulations, Section 5193)."

Staff recommends acceptance of this comment.

Comment 11:

The California Dental Association provided the following comment:

> 1005 (b) (6) – CDA suggests adding language to suggest/recommend DHCP thoroughly wash their hands with soap and water at the start of each work day. Further, "work restrictions" should be defined and/or CDC's guidelines cited. The sentence reads "CDC Guidelines shall be followed for work restrictions." It is unclear what is meant by "work restrictions."

Staff recommends acceptance of this comment and suggests the following modified text:

(6) All ~~Health care workers~~DHCP shall thoroughly wash their hands with soap and water at the start and end of each workday. DHCP shall wash contaminated or visibly soiled hands with soap and water and put on new gloves before treating each patient. If

hands are not visibly soiled or contaminated an alcohol based hand rub may be used as an alternative to soap and water. Hands shall be thoroughly dried before donning gloves in order to prevent promotion of bacterial growth and washed again immediately after glove removal. ~~CDC Guidelines shall be followed for work restrictions.~~ A DHCP shall refrain from direct patient care if conditions are present that may render the DHCP or patients more susceptible to opportunistic infection or exposure.

Comment 12:

The California Dental Association provided the following comment:

> Section 1005 (b) (8) – Remove the reference to "germicidal agents." Medical gloves do not protect against chemicals. Chemical-resistant and chemical compatible gloves should be worn when handling chemicals. Proposed Section 1005 (b) (4) already addresses this.
>
> CDA suggests changing "cleaning" to "processing contaminated" to distinguish handling instruments during patient treatment from processing/cleaning contaminated sharp instruments when treatment is completed.
>
> The following language is suggested:
>
> "(8) Medical exam gloves shall be worn whenever there is contact with mucous membranes, blood, or OPIM and during all pre-clinical, clinical, post-clinical, and laboratory procedures. When processing contaminated sharp instruments, needles, and devices, DHCP shall wear heavy-duty, puncture resistant utility gloves to prevent puncture wounds. Gloves must be discarded when torn or punctured, upon completion of treatment, and before leaving laboratories or areas of patient care activities. All DHCP shall perform hand hygiene procedures before donning gloves and after removing and discarding gloves. Gloves shall not be washed before or after use."

Staff recommends acceptance of this comment.

Comment 13:

The California Dental Association provided the following comment:

> Section 1005 (b) (9) – Requiring the use of "puncture-resistant" gloves when "cleaning" sharps implies that direct handling of sharps is acceptable. Language needs to be added, possibly to Section 1005 (b) (9), stating that Cal/OSHA prohibits direct handling of contaminated sharps.
>
> The following language is suggested:
>
> "(9) Needles shall be recapped only by using the scoop technique or a protective device. Needles shall not be bent or broken for the purpose of disposal. Sharps contaminated with blood or OPIM shall not be stored or processed in a manner that requires

employees to reach by hand into containers where these sharps have been placed. Disposable needles, syringes, scalpel blades, or other sharp items and instruments shall be placed into sharps containers for disposal as close as possible to the point of use according to all applicable local, state, and federal regulations."

Staff recommends rejection of this comment. Sharps containers are designed so that hands are not able to reach into the containers.

Comment 14:

The California Dental Association provided the following comment:

Section 1005 (b) (10) and 1005 (b) (11) – This language appears to require pre-packing of heat sensitive critical instruments processed by high-level disinfectants. Since the primary high-level disinfectants used in dentistry are chemical liquids, it is not clear how one would package and then process items using liquid high-level disinfectants. Since it is impossible and against such disinfectants label usage to effectively achieve liquid high-level disinfection if the instruments are pre-packaged, it cannot be determined how dentists and DHCPs can comply with this requirement.

Additionally, CDA suggests adding language to require event related or dated related labeling of each package. The Centers for Disease Control and Injury Prevention (CDC) recognizes that packaged instruments should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet packaging). CDC advises date and event-related packaging to include the date of sterilization and the sterilizer used if multiple sterilizers are used in the facility, on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure.

CDA encourages the Board to retain language allowing sterilized items to be placed "on a setup tray and covered with a moisture impervious barrier on the day the instruments will be used." Evidence to discontinue this practice does not exist.

Finally, CDA suggests changing "pre-clean" to simply "clean" or following "pre-clean" with "clean." If you "pre-clean" an item, it still needs to be cleaned. CDA also suggests removing or clarifying "in the form of package."

The following language is suggested:

"(10) After each use, critical items shall be discarded or cleaned, packaged or wrapped, and sterilized with proper labeling including the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in new wrap, and sterilized again. Methods of sterilization include steam under pressure, chemical vapor and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection. Critical instruments or containers of critical instruments sterilized by a heat or vapor method

shall be packaged or wrapped with proper labeling before sterilization if they are not to be used immediately after sterilization. These items shall remain sealed and stored in a manner so as to prevent contamination unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used."

"(11) After each use, semi-critical items shall be discarded or cleaned, packaged or wrapped, and sterilized with proper labeling including the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in new wrap, and sterilized again. Methods of sterilization include steam under pressure, chemical vapor and dry heat. If a semi-critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection. Semi-critical instruments or containers of semi-critical instruments sterilized by a heat or vapor method shall be packaged or wrapped with proper labeling before sterilization if they are not to be used immediately after sterilization. These items shall remain sealed and stored in a manner so as to prevent contamination unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used."

Staff recommends rejection of this comment. The Dental Hygiene Committee's suggested modified text specifies that the disinfection process must be complete before packaging or wrapping.

Comment 15:

The California Dental Association provided the following comment:

Section 1005 (b) (12) – Change the reference of the "United States Environmental Protection Agency" to "California Environmental Protection Agency (Cal/EPA)" to be legal and consistent with Section 1005 (b) (18). Legally, only Cal/EPA registered disinfectants are legal for use in California. Many disinfectants are registered with the Federal EPA, but do not meet California standards and are therefore illegal to purchase and use.

The following language is suggested:

"(12) Non-critical surfaces and patient care items shall be cleaned and disinfected with a California Environmental Protection Agency (Cal/EPA)-registered hospital disinfectant (low-level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, a Cal/EPA-registered hospital intermediate-level disinfectant with a tuberculocidal claim shall be used."

Staff recommends acceptance of this comment.

Comment 16:
The California Dental Association provided the following comment:

> Section 1005 (b) (13) – Delete "instrument" to be consistent with definition of "semi-critical item" in Section 1005 (a) (3).
>
> The following language is suggested:
>
> "(13) All high-speed dental hand pieces, low-speed hand pieces, rotary components, and dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged, labeled, and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item."

Staff recommends acceptance of this comment.

Comment 17:
The California Dental Association provided the following comment:

> 1005 (b) (15) – Remove the reference to "spore testing monitor, " changing it to read "spore test" as we are unaware of the existence of a "spore testing monitor."
>
> The following language is suggested:
>
> "(15) Proper functioning of sterilization cycle of all sterilization devices shall be verified at least weekly through the use of a biological indicator (such as a spore test). Test results shall be documented and maintained for 12 months."

Staff recommends acceptance of this comment.

Comment 18:
The California Dental Association provided the following comment:

> Section 1005 (b) (17) (18) – Move the third sentence "Products used to clean items or surfaces prior to disinfection procedures shall be clearly labeled and follow all material safety data sheet (MSDS) handling and storage instructions" to Section 1005 (b) (18) where cleaning is referenced. This section discusses barriers, not cleaning. Additionally, changing disposable barriers "when visibly soiled" is not necessary since the patient has not changed. Finally, to be consistent with 1005 (a) (8), 1005 (b) (18) should use the term "germicide" instead of "disinfectant."
>
> The following language is suggested:
>
> "(17) If non-critical items or surfaces likely to be contaminated are manufactured in a manner preventing cleaning and disinfection, they shall be protected with disposable impervious barriers. Disposable barriers shall be changed when visibly soiled or

damaged and between patients."

"(18) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a California Environmental Protection Agency (Cal-EPA) registered, hospital grade low- to intermediate-level germicide after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g. floors, walls, sinks) with a detergent and water or a Cal-EPA registered, hospital grade disinfectant. Products used to clean items or surfaces prior to disinfection shall be clearly labeled, and DHCP's shall follow all label and material safety data sheet (MSDS) handling and storage instructions."

Staff recommends rejection of this comment.

Comment 19:

The California Dental Association provided the following comment:

1005 (b) (21) – For the same reason listed above in Item #14, CDA suggests adding the language about labeling to this standard.

The following language is suggested:

"(21) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a sterilized, or new rag-wheel shall be used for each patient. Devices used to polish, trim or adjust contaminated intraoral devices shall be disinfected or sterilized, properly packaged or wrapped and properly labeled with the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in new wrap, and sterilized again. Sterilized items will be stored in a manner so as to prevent contamination."

Staff recommends acceptance of this comment.

COMMENTS RECEIVED FROM OSHA REVIEW INCORPORATED

Comment 1:

OSHA Review Incorporated provided the following comment:

Comment on Proposed Section 1005(a)(5) and 1005(a)(6):

Current Proposed Language Under Review:

(5) "Low-level disinfection" is the least effective disinfection process. It kills some bacteria, some viruses and fungi, but does not kill bacterial spores or mycobacterium

tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals.

(6) "Intermediate-level disinfection" kills mycobacterium tuberculosis var bovis indicating that many human pathogens are also killed. This process does not necessarily kill spores.

Recommended Changes:
(5)"Disinfection" describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. Factors that affect the efficacy of disinfection include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; presence of biofilms; and temperature and pH of the disinfection process.

Reasons:
Necessity/Clarity/Consistency: While we understand the importance and applicability of CDC's guidelines for dentistry (Guidelines for Infection Control in Dental Health-Care Settings – 2003 and Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008), it is important to note that CDC is a recommending body only, and when CDC recommendations directly conflict with legal requirements, the legal requirements must be followed.

The current regulation and the proposed language under review are unnecessary, confusing, and in conflict with State and Federal Law. The terms "low-level disinfection" and "intermediatelevel disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims. Stating that "low-level disinfectants kill "some" viruses and fungi" is unclear and inconsistent with State and Federal Law. Stating "intermediate-level disinfection kills mycobacterium tuberculosis var bovis indicates that many human pathogens are also killed" is also unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

Consistency: The recommended language for (5) comes directly from CDC guidelines (Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008) and Cal/OSHA's Bloodborne Pathogens Regulation and removes any potential illegal implications of efficacy in conflict with Cal/OSHA, Cal/EPA, Federal EPA, and FIFRA.

Staff recommend rejection of this comment. It is necessary to clearly delineate disinfection levels to be used during infection control practices in dental healthcare

settings. The suggested modifications diminishes the specificity of the definitions for disinfection.

Comment 2:
OSHA Review Incorporated provided the following comment:

> **Comment on Proposed Section 1005(a)(8):**
> **Current Proposed Language Under Review:**
> (8) "Germicide" is a chemical agent that can be used to disinfect items and surfaces based on the level of contamination. All germicides must be used in accordance with intended use and label instructions.
>
> **Recommended Changes:**
> (8) "Germicide" is a chemical sterilizing and/or disinfecting agent that can be used to sterilize and/or disinfect items and surfaces based on the level of contamination.
>
> **Reasons:**
> Consistency: As stated in CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, "In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and not those used on critical or semicritical medical devices; the latter are regulated by FDA." Under both CDC and Federal EPA definitions, a germicide can be used for sterilization and high level disinfection as defined by the US Food and Drug Administration (FDA), and also for surface disinfection as defined by Federal EPA and Cal/EPA.
>
> Additionally, we recommend the second sentence be removed because it is not part of the definition of "germicide", but is more of a practice standard that is addressed in Section 1005(b)(18).

Staff recommends rejection of this comment. The recommended change is unnecessary and does not make any substantive change.

Comment 3:
OSHA Review Incorporated provided the following comment:

> **Comment on Proposed Section 1005(b)(12):**
> **Current Proposed Language Under Review:**
> (12) Non-critical surfaces and patient care items shall be cleaned and disinfected with an United States Environmental Protection Agency (EPA)-registered hospital disinfectant (low-level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, an EPA-registered hospital disinfectant with a tuberculocidal claim (intermediate-level disinfectant) shall be used.

Recommended Changes:
(12) Non-critical surfaces and patient care items shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered as effective against tuberculosis var bovis or registered as effective against HIV and HBV. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions.

Reasons:
Necessity: Efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulation.

Clarity: It is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled (with Cal/EPA approved label) as a cleaner and disinfectant.

Consistency: While we understand the importance and applicability of CDC's guidelines for dentistry (Guidelines for Infection Control in Dental Health-Care Settings – 2003 and Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008), it is important to note that CDC is a recommending body only, and when CDC recommendations directly conflict with legal requirements, the legal requirements must be followed.

The current regulation and the proposed language under review are confusing and in conflict with State and Federal Law. The terms "low-level disinfection" and "intermediate-level disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims. Implying that an "EPA-registered hospital disinfectant with a tuberculocidal claim (intermediate-level disinfectant)" is efficacious for other target organisms which haven't been tested is unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 state that "virtually no risk has been documented for transmission of infectious agents to patients through noncritical items when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes" and go on to recommend that hospital grade disinfectants may beused to disinfect these surfaces (after cleaning of course).

Because cleaning is a necessary first step prior to disinfection which must be performed using a cleaning product (labeled as such), it is difficult to anticipate a case where a non-

critical surface or item would be visibly contaminated prior to disinfection, if cleaning is done prior to disinfection.

Consistency: The reference to US EPA is not legal, as all disinfectants and germicides used in California must be registered by Cal/EPA. All Cal/EPA registered disinfectants must have current US EPA registration, but not vice versa. Cal/EPA requirements are more stringent than Federal requirements.

Consistency: Additionally, it should be noted that, under new regulations from California Air Resources Board – Title 17 CCR Section 94509, many disinfectants that fall under the previous language as "intermediate-level" will fail to meet the states volatile organic compounds (VOC) emissions limits. The products that fail will no longer be available for sale or must be reformulated by manufacturers. For the dental industry, consumer and institutional non-aerosol disinfectants sold and/or used in California cannot have more than 1% of VOCs. The new limits for disinfectants and sanitizers took effect on December 31, 2009, which includes a year grace period for disinfectant products registered under FIFRA. The fine for violating air pollution regulations can be up to $50,000 per day, for each day a non-complying product is offered for sale. This new regulation is expected to have a drastic impact on the number of "intermediate level" disinfectants on the dental market.

Staff recommends rejection of this comment. The Dental Board does not regulate the effectiveness of the disinfectant. The Dental Board is not charged with the authority to enforce another agency's standards. The board does not set the minimum standards for disinfection and disinfection labels.

Comment 4:

OSHA Review Incorporated provided the following comment:

Comment on Proposed Section 1005(b)(18):

Current Proposed Language Under Review:

(18) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a California Environmental Protection Agency (Cal-EPA) registered, hospital grade lowto intermediate-level disinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g. floors, walls, sinks) with a detergent and water or a Cal-EPA registered, hospital grade disinfectant.

Recommended Changes:

(18) All clinical contact surfaces that are not protected by impervious barriers shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered effective against tuberculosis var bovis or registered against HIV and HBV. Disinfectants shall be

used in accordance with the manufacturer's intended use and label instructions. All housekeeping surfaces (e.g. floors, walls, sinks) shall be cleaned with a detergent and water or a Cal/EPA registered, hospital grade disinfectant.

Reasons:
Necessity: Efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulation.

Clarity: It is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled (with Cal/EPA approved label) as a cleaner and disinfectant.

Clarity: The language for (18) clarifies what type of disinfectant may be used on clinical contact surfaces.

Consistency: The terms "low-level disinfection" and "intermediate-level disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims. Implying that an "EPA-registered hospital disinfectant with a tuberculocidal claim (intermediate-level disinfectant)" is efficacious for other target organisms which haven't been tested is unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

Consistency: Additionally, it should be noted that, under new regulations from California Air Resources Board – Title 17 CCR Section 94509, many disinfectants that fall under the previous language as "intermediate-level" will fail to meet the states volatile organic compounds (VOC) emissions limits. The products that fail will no longer be available for sale or must be reformulated by manufacturers. For the dental industry, consumer and institutional non-aerosol disinfectants sold and/or used in California cannot have more than 1% of VOCs. The new limits for disinfectants and sanitizers took effect on December 31, 2009, which includes a year grace period for disinfectant products registered under FIFRA. The fine for violating air pollution regulations can be up to $50,000 per day, for each day a non-complying product is offered for sale. This new regulation is expected to have a drastic impact on the number of "intermediate level" disinfectants on the dental market.

Staff recommends rejection of this comment. The Dental Board does not regulate the effectiveness of the disinfectant. The Dental Board is not charged with the authority to enforce another agency's standards. The board does not set the minimum standards for disinfection and disinfection labels.

Comment 5:
OSHA Review Incorporated provided the following comment:

Comment on Proposed Section 1005(b)(22):
Current Proposed Language Under Review:
(22) All intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth.

Recommended Changes:
(22) All intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered effective against tuberculosis var bovis or registered against HIV and HBV before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions.

Reasons:

Necessity: Efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulation.

Clarity: Many "intermediate level" disinfectants are not cleaners. It is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled (with Cal/EPA approved label) as a cleaner and disinfectant.

Consistency: The terms "low-level disinfection" and "intermediate-level disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims and is unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

Consistency: It should be noted that, under new regulations from California Air Resources Board – Title 17 CCR Section 94509, many disinfectants that fall under the previous language as "intermediate-level" will fail to meet the states volatile organic compounds (VOC) emissions limits. The products that fail will no longer be available for

sale or must be reformulated by manufacturers. For the dental industry, consumer and institutional non-aerosol disinfectants sold and/or used in California cannot have more than 1% of VOCs. The new limits for disinfectants and sanitizers took effect on December 31, 2009, which includes a year grace period for disinfectant products registered under FIFRA. The fine for violating air pollution regulations can be up to $50,000 per day, for each day a non-complying product is offered for sale. This new regulation is expected to have a drastic impact on the number of "intermediate level" disinfectants on the dental market.

Consistency: All disinfectants used in California must be registered by Cal/EPA, to be consistent with existing laws and previous sections of Title 16, Division 10, California Code of Regulation, Section 1005 – Minimum Standards for Infection Control.

Point of Information: One factor commonly overlooked in choosing a surface disinfectant is the overall safety of the product to the environment and to staff members who are exposed to it daily over many years. Stronger disinfectants are not necessarily better, but are often more toxic. If "stronger" is the selection criteria for surface disinfectants, why would we not use sterilants, the "strongest" known chemical agents against pathogens? In general, the least toxic disinfectant for the specific target pathogens should be used to maximize occupational and environmental safety.

Stronger often means more hazardous to dental personnel. In some cases, the danger to staff members may be greater from the exposure to toxic disinfectants than any potentially infectious diseases. "Stronger is better" is neither used for prescribing pain medication nor other prescription drugs. The appropriate pain medication or therapeutic drug indicated is the compound that is specific to the medical requirement with the least hazardous side effect. Many "intermediate level disinfectants" contain organic solvents such as alcohols and/or phenols, which vaporize more readily, greatly affecting indoor air quality for the users and patients. Due to their flammability, most organic solvents cannot be discharged down the drain, and must be disposed as hazardous waste. O-phenylphenol, found in many tuberculocidal disinfectants, is listed on California's Proposition 65 List of known carcinogens. And with new VOC emissions limits, many will soon be taken off the market or reformulated.

Staff recommends rejection of this comment. The Dental Board does not regulate the effectiveness of the disinfectant. The Dental Board is not charged with the authority to enforce another agency's standards. The board does not set the minimum standards for disinfection and disinfection labels.

University of California
San Francisco
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Division of Orthodontics
Department of Orofacial Sciences

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To: Dental Board of California

30 August 2010

C/o Sarah Wallace
2005 Evergreen Street. Suite 1550
Sacramento, CA 95815

Re: Public Comment on proposed language changes to DBC Regulations Section 1005 of Title 16 of the California Code of Regulation.

Sterilization and Disinfection: Paragraph ~~(9)~~ (10)

This paragraph mandated that heat sensitive items must be processed ***with high level disinfection in the form of (a) package or being wrapped before sterilization.***

Please be aware that the conventional method of high level disinfection used for heat sensitive surgical instruments is complete submersion in a disinfectant for up to 12 hours.

Wrapping or packaging an item before submersion will do three things:

1. Severely restrict the disinfectant's ability to contact the contaminated instrument
2. Reduce the reliability of the disinfection process.
3. Create a very wet package that cannot be dried easily before storage and its ultimate use.

Proposal: Edit the regulatory text as follows:

If a critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection **and stored** in ~~the form of~~ a **wrapped** package or **cassette** ~~being wrapped before sterilization~~ if ~~they are~~ **it is** not to be used immediately after being sterilized.

Advantages:

1. The disinfection process will be unimpeded by the packaging / wrapping medium.
2. Consistent disinfection will be assured.
3. The disinfected items will be protected from re-contamination during storage.

Earl Johnson, DDS

Health Sciences Clinical Professor

October 6, 2010

Dental Board of California
Sarah Wallace, Legislative and Regulatory Analyst
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: Minimum Standards for Infection Control

Dear Ms. Wallace:

The California Dental Association (CDA) has reviewed the proposed changes to the Minimum Standards for Infection Control and offers the following suggestions:

1. 1005(a) (1) The new language in this paragraph uses the phrase "safe injection practices." CDA proposes revising the phrase to "safe handling of sharps" to broaden the focus from needles to all dental sharps.

2. Section 1005 (a) (2) – Add "instruments" in second sentence to be consistent with the definition in Section 1005 (a) (3).

   The following language is suggested:

   "'Critical items' confer a high risk for infection if they are contaminated with any microorganism. These include all instruments, devices, and other items used to penetrate soft tissue or bone."

3. Section 1005 (a) (5) – Delete "is the least effective disinfection process" as it is unnecessary. Neither the definition for intermediate-level disinfection nor the definition for high-level disinfection includes such a statement.

   The following language is suggested:

   "'Low-level disinfection' kills some bacteria, some viruses and fungi, but does not kill bacterial spores or mycobacterium tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals."

4. Section 1005 (a) (8) – Remove "germicides must be used in accordance with intended use and label instructions" from the second sentence. Section (a) is Definition of terms, while Section (b) are practice standards. Because this sentence is a practice standard, it should be moved to Section 1005 (b).

5. Section 1005 (a) (10) – Similar to #4 above, remove second and third sentences from Section 1005 (a) and move them to Section 1005 (b) because it is not part of the definition of "cleaning," but is a practice standard.

6. Section 1005 (a) (11) – Remove the examples contained within the parenthesis "(shoes, gowns/labcoats)" as they are unnecessary. Additionally any mention of gowns/labcoats should

be changed to "protective attire" to be consistent with Cal/OSHA's Bloodborne Pathogens Standard (Section 5193 Title 8 CCR).

Proposed Section 1005 (a) (11) references "shoes" without qualification or limitation. This section could be interpreted as employers are required to provide shoes to employees. Cal/OSHA requires employers to pay for the PPE employees must don to perform their job safely. Shoes are specified by Cal/OSHA for only those situations where it is reasonable to expect "gross" contamination such as in autopsies and orthopedic surgery.

Additionally, Section 1005 references both "gowns/labcoats" and "gowns", which creates confusion. Section 1005 (a) (11) uses the term "gowns/labcoats," while all other line items of this proposed regulation refer only to "gowns." It is unclear if those sections referring to "gowns" include "labcoats" or only "gowns."

Clarity and consistency are needed.

The following language is suggested:

"(11) "Personal Protective Equipment" (PPE) is specialized clothing or equipment worn or used for protection against a hazard. PPE items may include, but are not limited to, gloves, masks, respiratory devices, protective eyewear, and protective attire which are intended to prevent exposure to blood, body fluids, and OPIM, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants and shirts are not considered to be PPE."

7. 1005 (a) (12) "Other Potentially Infectious Materials" (OPIM) is defined in this section, but the proposed language fails to cover hepatitis B and C. In addition, the HIV section is worded awkwardly. CDA suggests adopting Cal/OSHA's definition in the Bloodborne Pathogens Standard (Section 5193 Title 8 CCR).

§5193. Bloodborne Pathogens.

"Other Potentially Infectious Materials" means:

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:

(A) Cell, tissue, or organ cultures from humans or experimental animals;

(B) Blood, organs, or other tissues from experimental animals; or

(C) Culture medium or other solutions.

8. Section 1005 (b) – This section needs clarity. Section (b) requires compliance with Cal/OSHA requirements for infection control, specifically bloodborne pathogens and aerosol transmitted diseases. Section 3384 Title 8 CCR is also pertinent because it specifies PPE requirements during chemical handling. Additionally, the California Division of Occupational Safety and Health is referred to as Cal/OSHA, not "Cal-DOSH."

   The following language is suggested:

   "(b) All DHCP shall comply with and enforce the California Division of Occupational Safety and Health (Cal/OSHA) requirements for infection control, as applicable, and the following minimum precautions to prevent the transmission of pathogens in health care settings."

9. Section 1005 (b) (4) – Clarify the PPE requirements for chemical handling. This section states that "puncture resistant utility gloves and other PPE shall be worn when handling hazardous chemicals." It is unclear as to what "other PPE" would be required under the new rules. CDA suggests "chemical-resistant utility gloves when handling hazardous chemicals, not "puncture resistant." "Other PPE" should be defined if that language remains.

   The following language is suggested:

   "(4) All DHCP shall wear surgical facemasks in combination with either chin length plastic face shields or protective eyewear whenever there is potential for aerosol spray, splashing or spattering of the following: droplet nuclei, blood, OPIM, or chemical or germicidal agents. Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals. After each patient, masks shall be changed and disposed. After each patient treatment, face shields and protective eyewear shall be cleaned and disinfected, or disposed."

10. Section 1005 (b) (5) – Change "gowns" to "protective attire" (see Item #6 above) and Cal-DOSH to Cal/OSHA (see Item #8 above). Additionally change "splattering" to "spattering" to be consistent with Section 1005 (b) (4).

    The following language is suggested:

    "(5) Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items. All DHCP shall wear reusable or disposable protective attire whenever there is a potential for aerosol spray, splashing or spattering of blood, OPIM, or chemicals and germicidal agents. Protective attire must be changed daily or between patients if it should become moist or visibly soiled. All PPE used during patient care shall be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with Cal/OSHA Bloodborne Pathogens Standards. (Title 8, California Code of Regulations, Section 5193)."

11. 1005 (b) (6) – CDA suggests adding language to suggest/recommend DHCP thoroughly wash their hands with soap and water at the start of each work day. Further, "work restrictions" should

be defined and/or CDC's guidelines cited. The sentence reads "CDC Guidelines shall be followed for work restrictions." It is unclear what is meant by "work restrictions."

12. Section 1005 (b) (8) – Remove the reference to "germicidal agents." Medical gloves do not protect against chemicals. Chemical-resistant and chemical compatible gloves should be worn when handling chemicals. Proposed Section 1005 (b) (4) already addresses this.

    CDA suggests changing "cleaning" to "processing contaminated" to distinguish handling instruments during patient treatment from processing/cleaning contaminated sharp instruments when treatment is completed.

    The following language is suggested:

    "(8) Medical exam gloves shall be worn whenever there is contact with mucous membranes, blood, or OPIM and during all pre-clinical, clinical, post-clinical, and laboratory procedures. When processing contaminated sharp instruments, needles, and devices, DHCP shall wear heavy-duty, puncture resistant utility gloves to prevent puncture wounds. Gloves must be discarded when torn or punctured, upon completion of treatment, and before leaving laboratories or areas of patient care activities. All DHCP shall perform hand hygiene procedures before donning gloves and after removing and discarding gloves. Gloves shall not be washed before or after use."

13. Section 1005 (b) (9) – Requiring the use of "puncture-resistant" gloves when "cleaning" sharps implies that direct handling of sharps is acceptable. Language needs to be added, possibly to Section 1005 (b) (9), stating that Cal/OSHA prohibits direct handling of contaminated sharps.

    The following language is suggested:

    "(9) Needles shall be recapped only by using the scoop technique or a protective device. Needles shall not be bent or broken for the purpose of disposal. Sharps contaminated with blood or OPIM shall not be stored or processed in a manner that requires employees to reach by hand into containers where these sharps have been placed. Disposable needles, syringes, scalpel blades, or other sharp items and instruments shall be placed into sharps containers for disposal as close as possible to the point of use according to all applicable local, state, and federal regulations."

14. Section 1005 (b) (10) and 1005 (b) (11) – This language appears to require pre-packing of heat sensitive critical instruments processed by high-level disinfectants. Since the primary high-level disinfectants used in dentistry are chemical liquids, it is not clear how one would package and then process items using liquid high-level disinfectants. Since it is impossible and against such disinfectants label usage to effectively achieve liquid high-level disinfection if the instruments are pre-packaged, it cannot be determined how dentists and DHCPs can comply with this requirement.

    Additionally, CDA suggests adding language to require event related or dated related labeling of each package. The Centers for Disease Control and Injury Prevention (CDC) recognizes that packaged instruments should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet packaging). CDC advises date and event-related packaging to include the date of sterilization and the sterilizer used if multiple sterilizers are used in the

facility, on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure.

CDA encourages the Board to retain language allowing sterilized items to be placed "on a setup tray and covered with a moisture impervious barrier on the day the instruments will be used." Evidence to discontinue this practice does not exist.

Finally, CDA suggests changing "pre-clean" to simply "clean" or following "pre-clean" with "clean." If you "pre-clean" an item, it still needs to be cleaned. CDA also suggests removing or clarifying "in the form of package."

The following language is suggested:

"(10) After each use, critical items shall be discarded or cleaned, packaged or wrapped, and sterilized with proper labeling including the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in new wrap, and sterilized again. Methods of sterilization include steam under pressure, chemical vapor and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection. Critical instruments or containers of critical instruments sterilized by a heat or vapor method shall be packaged or wrapped with proper labeling before sterilization if they are not to be used immediately after sterilization. These items shall remain sealed and stored in a manner so as to prevent contamination unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used."

"(11) After each use, semi-critical items shall be discarded or cleaned, packaged or wrapped, and sterilized with proper labeling including the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in new wrap, and sterilized again. Methods of sterilization include steam under pressure, chemical vapor and dry heat. If a semi-critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection. Semi-critical instruments or containers of semi-critical instruments sterilized by a heat or vapor method shall be packaged or wrapped with proper labeling before sterilization if they are not to be used immediately after sterilization. These items shall remain sealed and stored in a manner so as to prevent contamination unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used."

15. Section 1005 (b) (12) – Change the reference of the "United States Environmental Protection Agency" to "California Environmental Protection Agency (Cal/EPA)" to be legal and consistent with Section 1005 (b) (18). Legally, only Cal/EPA registered disinfectants are legal for use in California. Many disinfectants are registered with the Federal EPA, but do not meet California standards and are therefore illegal to purchase and use.

    The following language is suggested:

    "(12) Non-critical surfaces and patient care items shall be cleaned and disinfected with a California Environmental Protection Agency (Cal/EPA)-registered hospital disinfectant (low-

level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated

with blood or OPIM, a Cal/EPA-registered hospital intermediate-level disinfectant with a tuberculocidal claim shall be used."

16. Section 1005 (b) (13) – Delete "instrument" to be consistent with definition of "semi-critical item" in Section 1005 (a) (3).

    The following language is suggested:

    "(13) All high-speed dental hand pieces, low-speed hand pieces, rotary components, and dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged, labeled, and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item."

17. 1005 (b) (15) – Remove the reference to "spore testing monitor, " changing it to read "spore test" as we are unaware of the existence of a "spore testing monitor."

    The following language is suggested:

    "(15) Proper functioning of sterilization cycle of all sterilization devices shall be verified at least weekly through the use of a biological indicator (such as a spore test). Test results shall be documented and maintained for 12 months."

18. Section 1005 (b) (17) (18) – Move the third sentence "Products used to clean items or surfaces prior to disinfection procedures shall be clearly labeled and follow all material safety data sheet (MSDS) handling and storage instructions" to Section 1005 (b) (18) where cleaning is referenced. This section discusses barriers, not cleaning. Additionally, changing disposable barriers "when visibly soiled" is not necessary since the patient has not changed. Finally, to be consistent with 1005 (a) (8), 1005 (b) (18) should use the term "germicide" instead of "disinfectant."

    The following language is suggested:

    "(17) If non-critical items or surfaces likely to be contaminated are manufactured in a manner preventing cleaning and disinfection, they shall be protected with disposable impervious barriers. Disposable barriers shall be changed when visibly soiled or damaged and between patients."

    "(18) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a California Environmental Protection Agency (Cal-EPA) registered, hospital grade low- to intermediate-level germicide after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g. floors, walls, sinks) with a detergent and water or a Cal-EPA registered, hospital grade disinfectant. Products used to clean items or surfaces prior to disinfection shall be clearly labeled, and DHCP's shall follow all label and material safety data sheet (MSDS) handling and storage instructions."

19. 1005 (b) (21) – For the same reason listed above in Item #14, CDA suggests adding the language about labeling to this standard.

The following language is suggested:

"(21) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a sterilized, or new rag-wheel shall be used for each patient. Devices used to polish, trim or adjust contaminated intraoral devices shall be disinfected or sterilized, properly packaged or wrapped and properly labeled with the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in new wrap, and sterilized again. Sterilized items will be stored in a manner so as to prevent contamination."

Thank you for considering these changes. If you have any questions, please contact me at 916-554-4989 or dean.chalios@cda.org.

Sincerely,

Dean Chalios
Vice President, Public Policy

Dental Assisting ALLIANCE

California Dental Assistants Association (CDAA)
Expanded Functions Dental Assistants Association (EFDAA)

October 9, 2010

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

Re: Comment on Proposed Changes to Regulation Section 1005 to be heard October 11, 2010

The Alliance has the following comment regarding the Board's proposed changes to regulation Section 1005. Minimum Standards for Infection Control.

Subdivisions (b)(10) and (11) are incorrect, and therefore unclear.

It is not appropriate or effective to wrap a heat-sensitive item before high-level disinfection or sterilization of the item, since the method of high level disinfection or sterilization for heat-sensitive items is by immersion in a liquid chemical sterilant/disinfectant.

It is also inconsistent with CDC Guidelines to wrap instruments after high level disinfection or cold sterile processing. According to CDC Guidelines *"If stored before use, the instrument should not be considered sterile and should be sterilized again just before use".*

Also, critical items must be sterilized with an FDA cleared chemical.

Following is our suggested revised language for each of the subdivisions, without strikeout or underline:

(10) Critical instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include steam under pressure (autoclaving), chemical (formaldehyde) vapor, and dry heat. These instruments, items, and devices shall be packaged or wrapped before sterilization if they are not to be used immediately after sterilization and shall remain sealed until the day of use and stored in a manner so as to prevent contamination. If a critical item is heat sensitive, it shall, at minimum, be processed with an FDA cleared chemical sterilant to achieve sterilization, and if not used immediately, shall be re-processed immediately prior to use.

(11) Semi-critical items shall be pre-cleaned, packaged or wrapped, and sterilized after each use. Methods of sterilization include steam under pressure, chemical vapor and dry heat. These

instruments, items, and devices shall be packaged or wrapped before sterilization if they are not to be used immediately after sterilization and shall remain sealed until the day of use and stored in a manner so as to prevent contamination. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with an FDA cleared chemical steriliant/disinfectant to achieve high level disinfection.

Sincerely,

Leslie Canham

Leslie Canham, RDA
Representing CDAA
(888) 853-7543

Joan Greenfield

Joan Greenfield, RDAEF
Representing EFDAA
(916) 837-7171

DHCC recommendations are highlighted in blue.

CADAT recommendations are highlighted in yellow.

Sterilization and Disinfection:

~~(9)~~(10) ~~Heat stable c~~Critical ~~and semi critical~~ instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include ~~shall be cleaned and sterilized before use by using~~ steam under pressure (autoclaving), ~~dry heat, or~~ chemical (formaldehyde) vapor and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection ~~and packaged or wrapped~~ upon completion of the disinfection process. ~~in the form of package, or being wrapped before Sterilization if they are not to be used immediately after being sterilized.~~ These instruments, items and devices, shall remain sealed and stored in a manner so as to prevent contamination. ~~FDA cleared chemical sterilants/disinfectants shall be used for sterilization of heat sensitive critical items and for high level disinfection of heat sensitive semi critical items.~~

~~10)~~(11) ~~Critical and s~~Semi-critical ~~instruments or containers of critical and semi critical instruments~~ items shall be pre-cleaned, packaged or wrapped and sterilized after each use. ~~by a heat or vapor m~~Methods of sterilization include steam under pressure, chemical vapor and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection ~~and packaged or wrapped~~ upon completion of the disinfection process. ~~shall be packaged or wrapped in the form of package, or being wrapped before Sterilization before sterilization if they are not to be used immediately after being sterilized.~~ These packages or containers shall remain sealed ~~unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used~~ and shall be stored in a manner so as to prevent contamination.

Rationale: recommended revisions help to make distinctions between the disinfection and sterilization process, and reemphasize the necessity of packaging, wrapping or using a sealed container (semi-critical items) after the disinfection process.

CADAT

October 11, 2010

Dr. John Bettinger, President
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: Proposed Amendments to CCR Section 1005, Div. 10 of Title 16: Infection Control Regulations

Dear Dr. Bettinger and Members of the Dental Board of California:

During the July 26, 2010 Dental Board meeting, CADAT provided input as to the proposed amendments brought forth pertaining to the Board's Infection Control regulations. During testimony, a procedural/technical error was identified and discussed; specifically, language pertaining to critical and semi-critical instrument pre-cleaning, packaging, wrapping and sterilization was identified as being procedurally incorrect and probably the result of errors during the publication process.

The amended and published language set for public comment today has not addressed the erroneous language. CADAT did propose corrective language to the Dental Hygiene Committee (DHCC) at its recent meeting on September 28, 2010 and as such the DHCC approved corrective language. CADAT supports the DHCC-approved language, indicated below as single-underlined text, with slight amendments for clarity and consistency as indicated by double-underline below:

Proposed CCR Section 1005(b)(10 – 11):

~~(9)~~(10) ~~Heat stable c~~Critical ~~and semi-critical~~ instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include ~~shall be cleaned and sterilized before use by using~~ steam under pressure (autoclaving), ~~dry heat, or~~ chemical (formaldehyde) vapor and dry heat. If a critical item is heat sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. ~~in the form of package or being wrapped before sterilization if they are not to be used immediately after being sterilized.~~ These instruments, items and devices shall remain sealed and shall be stored in a manner so as to prevent contamination. ~~FDA cleared chemical sterilants/disinfectants shall be used for sterilization of heat sensitive crucial items and for high level disinfection of heat sensitive semi critical items.~~

~~(10)~~(11) ~~Critical and s~~Semi critical instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include steam under pressure (autoclaving), chemical (formaldehyde) vapor and dry heat. If a semi-critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. ~~in the form of package or being wrapped before sterilization if they are not to be used immediately after being sterilized.~~ These instruments, items and devices shall remain sealed and shall be

stored in a manner so as to prevent contamination. ~~FDA cleared chemical sterilants/disinfectants shall be used for sterilization of heat sensitive crucial items and for high level disinfection of heat sensitive semi critical items.~~

Rationale: The proposed language provided herein provides the procedurally correct language necessary to meet the stated objective, provides clarity for the user, and with the small changes proposed is more consistent with technically correct procedures used in sterilization and disinfection processes. Without correction, the published language is not procedurally correct.

Thank you for the opportunity to provide input and we look forward to the regulatory process in the coming months.

Respectfully submitted,

Lorraine Gagliardi

Lorraine Gagliardi, CDA, RDA, RDH, Ed.D.
Director – Policy Council

LaDonna Drury-Klein

LaDonna Drury-Klein, CDA, RDA, BS
President

Tamara McNealy

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October 11, 2010

To: Dental Board of California

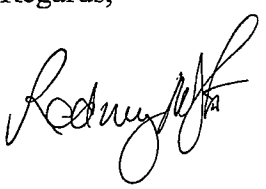
Re: Proposed Regulation: Title 16, Division 10, California Code of Regulations, Section 1005 – Minimum Standards for Infection Control

Dear Members of the Board:

We understand and know the importance of preventing infections in the dental office and that the board has developed rules for infection control to ensure patient safety and to comply with B&P Code Sections 1680 (t) and (dd). Your hard work and time is appreciated, as is the opportunity to comment upon the proposed rules.

We submit the following comments on the proposed regulation: Title 16, Division 10, California Code of Regulation, Section 1005 – Minimum Standards for Infection Control. The purpose of our comments is to ensure that the proposed regulation meets the California Administrative Procedure Act's (APA's) rulemaking procedures and standards for state agencies in California to ensure that proposed regulations are clear, necessary and legally valid. As we are educators, we will focus mostly on the need for "clarity", "consistency" and "non-duplication" of the proposed rules.

Regards,



Rodney M. Stine, President
OSHA Review, Inc.

Comment on Proposed Section 1005(a)(5) and 1005(a)(6):

Current Proposed Language Under Review:

(5) "Low-level disinfection" is the least effective disinfection process. It kills some bacteria, some viruses and fungi, but does not kill bacterial spores or mycobacterium tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals.

(6) "Intermediate-level disinfection" kills mycobacterium tuberculosis var bovis indicating that many human pathogens are also killed. This process does not necessarily kill spores.

Recommended Changes:

(5)"Disinfection" describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. Factors that affect the efficacy of disinfection include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; presence of biofilms; and temperature and pH of the disinfection process.

Reasons:

Necessity/Clarity/Consistency: While we understand the importance and applicability of CDC's guidelines for dentistry (*Guidelines for Infection Control in Dental Health-Care Settings – 2003* and *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*), it is important to note that CDC is a recommending body only, and when CDC recommendations directly conflict with legal requirements, the legal requirements must be followed.

The current regulation and the proposed language under review are unnecessary, confusing, and in conflict with State and Federal Law. The terms "low-level disinfection" and "intermediate-level disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims. Stating that "low-level disinfectants kill "some" viruses and fungi" is unclear and inconsistent with State and Federal Law. Stating "intermediate-level disinfection kills mycobacterium tuberculosis var bovis indicates that many human pathogens are also killed" is also unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

Consistency: The recommended language for (5) comes directly from CDC guidelines (*Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*) and Cal/OSHA's Bloodborne Pathogens Regulation and removes any potential illegal implications of efficacy in conflict with Cal/OSHA, Cal/EPA, Federal EPA, and FIFRA.

Comment on Proposed Section 1005(a)(8):

Current Proposed Language Under Review:

(8) "Germicide" is a chemical agent that can be used to disinfect items and surfaces based on the level of contamination. All germicides must be used in accordance with intended use and label instructions.

Recommended Changes:

(8) "Germicide" is a chemical sterilizing and/or disinfecting agent that can be used to sterilize and/or disinfect items and surfaces based on the level of contamination.

Reasons:

Consistency: As stated in CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008,* "In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and not those used on critical or semicritical medical devices; the latter are regulated by FDA." Under both CDC and Federal EPA definitions, a germicide can be used for sterilization and high level disinfection as defined by the US Food and Drug Administration (FDA), and also for surface disinfection as defined by Federal EPA and Cal/EPA.

Additionally, we recommend the second sentence be removed because it is not part of the definition of "germicide", but is more of a practice standard that is addressed in Section 1005(b)(18).

Comment on Proposed Section 1005(b)(12):

Current Proposed Language Under Review:

(12) Non-critical surfaces and patient care items shall be cleaned and disinfected with an United States Environmental Protection Agency (EPA)-registered hospital disinfectant (low-level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, an EPA-registered hospital disinfectant with a tuberculocidal claim (intermediate-level disinfectant) shall be used.

Recommended Changes:

(12) Non-critical surfaces and patient care items shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered as effective against tuberculosis var bovis or registered as effective against HIV and HBV. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions.

Reasons:

Necessity: Efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulation.

Clarity: It is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled (with Cal/EPA approved label) as a cleaner and disinfectant.

Consistency: While we understand the importance and applicability of CDC's guidelines for dentistry (*Guidelines for Infection Control in Dental Health-Care Settings – 2003* and *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*), it is important to note that CDC is a recommending body only, and when CDC recommendations directly conflict with legal requirements, the legal requirements must be followed.

The current regulation and the proposed language under review are confusing and in conflict with State and Federal Law. The terms "low-level disinfection" and "intermediate-level disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims. Implying that an "EPA-registered hospital disinfectant with a tuberculocidal claim (intermediate-level disinfectant)" is efficacious for other target organisms which haven't been tested is unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* state that "virtually no risk has been documented for transmission of infectious agents to patients through noncritical items when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes" and go on to recommend that hospital grade disinfectants may be used to disinfect these surfaces (after cleaning of course).

Because cleaning is a necessary first step prior to disinfection which must be performed using a cleaning product (labeled as such), it is difficult to anticipate a case where a non-critical surface or item would be visibly contaminated prior to disinfection, if cleaning is done prior to disinfection.

Consistency: The reference to US EPA is not legal, as all disinfectants and germicides used in California must be registered by Cal/EPA. All Cal/EPA registered disinfectants must have current US EPA registration, but not vice versa. Cal/EPA requirements are more stringent than Federal requirements.

Consistency: Additionally, it should be noted that, under new regulations from California Air Resources Board – *Title 17 CCR Section 94509*, many disinfectants that fall under the previous language as "intermediate-level" will fail to meet the states volatile organic compounds (VOC) emissions limits. The products that fail will no longer be available for sale or must be

reformulated by manufacturers. For the dental industry, consumer and institutional non-aerosol disinfectants sold and/or used in California cannot have more than 1% of VOCs. The new limits for disinfectants and sanitizers took effect on December 31, 2009, which includes a year grace period for disinfectant products registered under FIFRA. The fine for violating air pollution regulations can be up to $50,000 per day, for each day a non-complying product is offered for sale. This new regulation is expected to have a drastic impact on the number of "intermediate level" disinfectants on the dental market.

Comment on Proposed Section 1005(b)(18):

Current Proposed Language Under Review:

(18) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a California Environmental Protection Agency (Cal-EPA) registered, hospital grade low- to intermediate-level disinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g. floors, walls, sinks) with a detergent and water or a Cal-EPA registered, hospital grade disinfectant.

Recommended Changes:

(18) All clinical contact surfaces that are not protected by impervious barriers shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered effective against tuberculosis var bovis or registered against HIV and HBV. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions. All housekeeping surfaces (e.g. floors, walls, sinks) shall be cleaned with a detergent and water or a Cal/EPA registered, hospital grade disinfectant.

Reasons:

Necessity: Efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulation.

Clarity: It is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled (with Cal/EPA approved label) as a cleaner and disinfectant.

Clarity: The language for (18) clarifies what type of disinfectant may be used on clinical contact surfaces.

Consistency: The terms "low-level disinfection" and "intermediate-level disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims. Implying that an

"EPA-registered hospital disinfectant with a tuberculocidal claim (intermediate-level disinfectant)" is efficacious for other target organisms which haven't been tested is unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

Consistency: Additionally, it should be noted that, under new regulations from California Air Resources Board – *Title 17 CCR Section 94509*, many disinfectants that fall under the previous language as "intermediate-level" will fail to meet the states volatile organic compounds (VOC) emissions limits. The products that fail will no longer be available for sale or must be reformulated by manufacturers. For the dental industry, consumer and institutional non-aerosol disinfectants sold and/or used in California cannot have more than 1% of VOCs. The new limits for disinfectants and sanitizers took effect on December 31, 2009, which includes a year grace period for disinfectant products registered under FIFRA. The fine for violating air pollution regulations can be up to $50,000 per day, for each day a non-complying product is offered for sale. This new regulation is expected to have a drastic impact on the number of "intermediate level" disinfectants on the dental market.

Comment on Proposed Section 1005(b)(22):

Current Proposed Language Under Review:

(22) All intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth.

Recommended Changes:

(22) All intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered effective against tuberculosis var bovis or registered against HIV and HBV before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions.

Reasons:

Necessity: Efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulation.

Clarity: Many "intermediate level" disinfectants are not cleaners. It is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled (with Cal/EPA

approved label) as a cleaner and disinfectant.

Consistency: The terms "low-level disinfection" and "intermediate-level disinfection" are not recognized by US EPA, Cal/EPA, or Cal/OSHA. Under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. This prohibition includes third parties implying efficacy not supported by a disinfectant's label claims and is unsupportable scientifically under Cal/EPA labeling requirements and illegal under FIFRA (Federal Register 19174/ Vol. 51, No. 102/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162).

Consistency: It should be noted that, under new regulations from California Air Resources Board – *Title 17 CCR Section 94509*, many disinfectants that fall under the previous language as "intermediate-level" will fail to meet the states volatile organic compounds (VOC) emissions limits. The products that fail will no longer be available for sale or must be reformulated by manufacturers. For the dental industry, consumer and institutional non-aerosol disinfectants sold and/or used in California cannot have more than 1% of VOCs. The new limits for disinfectants and sanitizers took effect on December 31, 2009, which includes a year grace period for disinfectant products registered under FIFRA. The fine for violating air pollution regulations can be up to $50,000 per day, for each day a non-complying product is offered for sale. This new regulation is expected to have a drastic impact on the number of "intermediate level" disinfectants on the dental market.

Consistency: All disinfectants used in California must be registered by Cal/EPA, to be consistent with existing laws and previous sections of Title 16, Division 10, California Code of Regulation, Section 1005 – Minimum Standards for Infection Control.

Point of Information: One factor commonly overlooked in choosing a surface disinfectant is the overall safety of the product to the environment and to staff members who are exposed to it daily over many years. Stronger disinfectants are not necessarily better, but are often more toxic. If "stronger" is the selection criteria for surface disinfectants, why would we not use sterilants, the "strongest" known chemical agents against pathogens? In general, the least toxic disinfectant for the specific target pathogens should be used to maximize occupational and environmental safety.

Stronger often means more hazardous to dental personnel. In some cases, the danger to staff members may be greater from the exposure to toxic disinfectants than any potentially infectious diseases. "Stronger is better" is neither used for prescribing pain medication nor other prescription drugs. The appropriate pain medication or therapeutic drug indicated is the compound that is specific to the medical requirement with the least hazardous side effect.

Many "intermediate level disinfectants" contain organic solvents such as alcohols and/or phenols, which vaporize more readily, greatly affecting indoor air quality for the users and patients. Due to their flammability, most organic solvents cannot be discharged down the drain, and must be disposed as hazardous waste. O-phenylphenol, found in many tuberculocidal disinfectants, is listed on California's Proposition 65 List of known carcinogens. And with new VOC emissions limits, many will soon be taken off the market or reformulated.

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MEMORANDUM

DATE	October 27, 2010
TO	Dental Board Members Dental Board of California
FROM	Sarah Wallace Legislative & Regulatory Analyst
SUBJECT	**Agenda Item 4(B):** Discussion and Possible Action to Consider Adoption of Amendments to Title 16, CCR Section 1005 for the Minimum Standards for Infection Control

Background

Following the Board's consideration of comments received during the required 45-day public comment period, the Board may hold discussion and take action to adopt proposed amendments to Title 16, CCR Section 1005 for the Minimum Standards for Infection Control.

Board Action Requested

Depending on the Board's action, staff requests one of the following:

A. If the Board adopts the final text as noticed and no changes are made, the Board must direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law and authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed amendments to Title 16, CCR, Section 1005.

B. If the Board makes changes at the meeting to the text in response to any comments received, the Board must direct staff to take all steps necessary to complete the rulemaking process, including preparing a modified text for a 15-day public comment period, which includes the amendments accepted by the board at this meeting. 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 before completing the rulemaking process, and adopt amendments to Title 16, CCR, Section 1005.

TITLE 16. DENTAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

MODIFIED TEXT

Changes to the originally proposed language are shown by double underline for new text and double strikeout for deleted text.

Amend Section 1005 of Division 10 of Title 16 of the California Code of Regulations, to read as follows:

ARTICLE 1. GENERAL PROVISIONS

§ 1005. Minimum Standards for Infection Control

(a) Definitions of terms used in this section:

(1) "Standard precautions" is a ~~set of combined precautions that include the major components of universal precautions (designed to reduce the risk of transmission of blood-borne pathogens) and body substance isolation (designed to reduce the risk of transmission of pathogens from moist body substances). Include a~~ group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered. These include: hand hygiene, use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure: and safe handling of sharps~~injection practices~~. ~~Similar to universal precautions,~~ Sstandard precautions ~~are~~ shall be used for care of all patients regardless of their diagnoses ~~of~~ or personal infectious status.

(2) "Critical ~~instruments~~ items" confer a high risk for infection if they are contaminated with any microorganism. These include all instruments, ~~are surgical~~ devices, and other ~~instruments~~ items used to penetrate soft tissue or bone.

(3) "Semi-critical ~~instruments~~ items" are ~~surgical~~ instruments, devices and other ~~instruments~~ items that are not used to penetrate soft tissue or bone, but contact oral ~~tissue~~ mucous membranes, non-intact skin or other potentially infectious materials (OPIM).

(4) "Non-critical ~~instruments~~ items ~~and devices~~" are instruments, ~~and~~ devices, equipment, and surfaces that come in contact with soil, debris, saliva, blood, OPIM and intact skin, but not oral mucous membranes.

(5) "Low-level disinfection" is the least effective disinfection process~~;~~. It kills some bacteria, some viruses and fungi, but does not kill bacterial spores or mycobacterium tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals.

(6) "Intermediate-level disinfection" kills mycobacterium tuberculosis var bovis indicating that many human pathogens are also killed~~,~~. This process ~~but~~ does not necessarily kill spores.

(7) "High-level disinfection" kills some, but not necessarily all bacterial spores. This process kills mycobacterium tuberculosis var bovis, bacteria, fungi, and viruses.

(8) "Germicide" is a chemical agent that can be used to disinfect items and surfaces based on the level of contamination. ~~All germicides must be used in accordance with intended use and label instructions.~~

(9) "Sterilization" ~~kills all forms of microbial life.~~ is a validated process used to render a product free of all forms of viable microorganisms.

(10) "Cleaning" is the removal of visible soil (e.g., organic and inorganic material) debris and OPIM from objects and surfaces and shall be accomplished manually or mechanically using water with detergents or enzymatic products. ~~Cleaning must precede any disinfection or sterilization process. Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions.~~

~~(10)~~(11) "Personal Protective Equipment" (PPE) is specialized clothing or equipment worn of used for protection against a hazard. PPE includes items may include, but are not limited to, ~~such as~~ gloves, masks, respiratory devices, protective eyewear and protective attire ~~(shoes, gowns/labcoats)~~ which are intended to prevent exposure to blood, ~~and~~ body fluids~~.~~ and OPIM, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants and shirts, are not considered to be PPE.

~~(11)~~(12) "Other Potentially Infectious Materials" (OPIM) means any one of the following:

(A) H~~h~~uman body fluids such as saliva in dental procedures and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids~~;~~.

(B) A~~a~~ny unfixed tissue or organ (other than intact skin) from a human (living or dead)~~;~~.

(C) ~~Human Immunodeficiency Virus (HIV) containing cell or tissue cultures, organ culture and blood, or other tissues from experimental animals~~ Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:

(i) Cell, tissue, or organ cultures from humans or experimental animals;

(ii) Blood, organs, or other tissues from experimental animals; or

(iii) Culture medium or other solutions..

(13) "Dental Healthcare Personnel" (DHCP), are "all paid and non-paid personnel in the dental health-care setting who might be occupationally exposed to infectious materials, including body substances and contaminated supplies, equipment, environmental surfaces, water, or air. DHCP includes dentists, dental hygienists, dental assistants, dental laboratory technicians (in-office and commercial), students and trainees, contractual personnel, and other persons not directly involved in patient care but potentially exposed to infectious agents (e.g., administrative, clerical, housekeeping, maintenance, or volunteer personnel)."

(b) All DHCP ~~Licensees~~ shall comply with infection control precautions and enforce the following minimum precautions to minimize the transmission of pathogens in health care settings mandated by the California Division of Occupational Safety and Health (~~Cal-DOSH~~Cal/OSHA).

~~(c) All licensees shall comply with and enforce the following minimum precautions to minimize the transmission of pathogens in health care settings:~~

(1) Standard precautions shall be practiced in the care of all patients.

(2) A written protocol shall be developed, ~~by the licensee~~ maintained, and periodically updated for proper instrument processing, operatory cleanliness, and management of injuries. The protocol shall be made available to all DHCP at the dental office.

(3) A copy of this regulation shall be conspicuously posted in each dental office.

Personal Protective Equipment:

(4) All ~~Health care workers~~DHCP shall wear surgical facemasks in combination with either chin length plastic face shields or protective eyewear ~~when treating patients~~ whenever there is potential for aerosol spray, splashing or spattering of the following: droplet nuclei, blood, chemical or germicidal agents or OPIM. Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals. ~~Puncture-resistant utility gloves and other PPE shall be worn when handling hazardous chemicals.~~ After each patient~~,~~ ~~and during patient~~ treatment ~~if applicable,~~ masks shall be changed and disposed. ~~if moist or contaminated.~~ After each patient~~,~~ treatment, ~~and~~ face shields and protective eyewear shall be cleaned, ~~and~~ disinfected, ~~if contaminated~~ or disposed.

(5) ~~Gowns~~ Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items. All ~~Health care workers~~ DHCP shall wear reusable or disposable protective attire whenever there is a potential for aerosol spray, splashing or splattering of blood, OPIM, or chemicals and germicidal agents. ~~their clothing or skin is likely to be soiled with blood~~

~~or OPIM. Gowns~~ Protective attire must be changed daily or between patients if ~~it~~ they should become moist or visibly soiled. ~~Protective attire~~ All PPE used during patient care ~~must~~ shall be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with ~~Cal-DOSH~~ Cal/OSHA Bloodborne Pathogens Standards~~.~~ (Title 8, Cal. Code Regs., section 5193).

Hand Hygiene:

(6) All ~~Health care workers~~DHCP shall thoroughly wash their hands with soap and water at the start and end of each workday. DHCP shall wash contaminated or visibly soiled hands with soap and water and put on new gloves before treating each patient. If hands are not visibly soiled or contaminated an alcohol based hand rub may be used as an alternative to soap and water. Hands shall be thoroughly dried before donning gloves in order to prevent promotion of bacterial growth and washed again immediately after glove removal. ~~CDC Guidelines shall be followed for work restrictions.~~ A DHCP shall refrain from direct patient care if conditions are present that may render the DHCP or patients more susceptible to opportunistic infection or exposure.

(7) All ~~Health care workers~~DHCP who have exudative lesions or weeping dermatitis of the hand shall refrain from all direct patient care and from handling patient care equipment until the condition resolves.

Gloves:

(8) Medical exam gloves shall be worn whenever there is ~~a potential for~~ contact with mucous membranes, blood, ~~or~~ OPIM~~.~~, ~~or germicidal agents~~ and during all pre-clinical, clinical, post-clinical, and laboratory procedures. When ~~cleaning~~ processing contaminated sharp instruments, needles, and devices, DHCP shall wear heavy-duty utility gloves to prevent puncture wounds. Gloves must be discarded when torn or punctured, upon completion of treatment, and before leaving laboratories or areas of patient care activities. All ~~Healthcare workers~~ DHCP shall perform hand hygiene procedures before donning gloves and after removing and discarding gloves. Gloves shall not be washed before or after use.

Needle and Sharps Safety:

(9) Needles shall be recapped only by using the scoop technique or a protective device. Needles shall not be bent or broken for the purpose of disposal. Disposable needles, syringes, scalpel blades, or other sharp items and instruments shall be placed into sharps containers for disposal as close as possible to the point of use according to all applicable local, state, and federal regulations.

Sterilization and Disinfection:

(10) All germicides must be used in accordance with intended use and label instructions.
(11) Cleaning must precede any disinfection or sterilization process. Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions.

~~(9)~~~~(10)~~(12) ~~Heat-stable c~~Critical ~~and semi-critical~~ instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include ~~shall be cleaned and sterilized before use by using~~ steam under pressure (autoclaving), ~~dry heat, or~~ chemical (formaldehyde) vapor, and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. ~~in the form of package or being wrapped before sterilization if they are not to be used immediately after being sterilized.~~ These instruments, items, and devices, shall remain sealed and stored in a manner so as to prevent contamination. ~~FDA cleared chemical sterilants/disinfectants shall be used for sterilization of heat sensitive critical items and for high level disinfection of heat sensitive semi critical items.~~

~~(10)~~~~(11)~~(13) ~~Critical and s~~Semi-critical ~~instruments or containers of critical and semi critical instruments~~ instruments, items, and devices shall be pre-cleaned, packaged or wrapped and sterilized after each use. ~~by a heat or vapor m~~Methods of sterilization include steam under pressure (autoclaving), chemical vapor (formaldehyde) and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection and packaged or wrapped upon completion of the disinfection process. ~~Shall be packaged or wrapped in the form of package or being wrapped before sterilization. Before sterilization if they are not to be used immediately after being sterilized.~~ These packages or containers shall remain sealed ~~unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used~~ and shall be stored in a manner so as to prevent contamination.

~~(12)~~(14) Non-critical surfaces and patient care items shall be cleaned and disinfected with ~~an United States Environmental Protection Agency (EPA)~~ California Environmental Protection Agency (Cal/EPA)-registered hospital disinfectant (low-level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, a~~n~~ Cal/EPA-registered hospital intermediate-level disinfectant with a tuberculocidal claim ~~(intermediate-level disinfectant)~~ shall be used.

~~(11)~~~~(13)~~(15) All high-speed dental hand pieces, low-speed hand pieces, rotary components ~~used intraorally,~~ and ~~other~~ dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged and heat-sterilized ~~between patients.~~ in a manner consistent with the same sterilization practices as a semi-critical ~~instrument or~~ item.

~~(12)~~~~(14)~~(16) Single use disposable ~~instruments~~ items such as ~~(e.g.~~ prophylaxis angles, prophylaxis cups and brushes, tips for high-speed evacuators, saliva ejectors, air/water syringe tips, and gloves~~)~~ shall be used for one patient only and discarded.

~~(13) Needles shall be recapped only by using the scoop technique or a protective device. Needles shall not be bent or broken for the purpose of disposal. Disposable needles, syringes, scalpel blades or other sharp items and instruments shall be placed into sharps containers for disposal according to all applicable regulations.~~

~~(14)~~~~(15)~~(17) Proper functioning of the sterilization cycle of all sterilization devices shall be verified at least weekly through the use of a biological indicator (such as a spore test~~ing monitor~~). Test results ~~must~~ shall be documented and maintained for 12 months.

Irrigation:

~~(15)~~~~(16)~~(18) Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone. Sterile coolants/irrigants must be delivered using a sterile delivery system.

Facilities:

~~(16)~~~~(17)~~(19) If non-critical items or surfaces likely to be contaminated are ~~difficult~~ manufactured in a manner preventing cleaning and disinfection, ~~to clean and disinfect~~ they shall be protected with disposable impervious barriers. Disposable barriers shall be changed when visibly soiled or damaged and between patients. Products used to clean items or surfaces prior to disinfection procedures shall be clearly labeled and follow all material safety data sheet (MSDS) handling and storage instructions.

~~(17)~~~~(18)~~(20) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a California Environmental Protection Agency (Cal-EPA) registered, hospital grade low- to intermediate-level disinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g. floors, walls, sinks) with a detergent and water or a Cal-EPA registered, hospital grade disinfectant.

~~(18)~~~~(19)~~(21) Dental unit water lines shall be anti-retractive. At the beginning of each workday, dental unit lines and devices shall be purged with air~~,~~ or flushed with water for at least two (2) minutes prior to attaching handpieces, scalers, air water syringe tips, ~~and~~ or other devices. The dental unit lines and devices shall be flushed between each patient for a minimum of twenty (20) seconds.

~~(19)~~~~(20)~~(22) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.

Lab Areas:

~~(20)(21)~~(23) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a ~~disinfected, sterilized,~~ or new rag-wheel shall be used for each patient. Devices used to polish, trim, or adjust contaminated intraoral devices shall be disinfected or sterilized, properly packaged or wrapped and properly labeled with the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in new wrap, and sterilized again. Sterilized items will be ~~and~~ stored in a manner so as to prevent contamination.

~~(21)(22)~~(24) All ~~i~~Intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth.

(d) The Dental Board of California and Dental Hygiene Committee of California shall review this regulation annually and establish a consensus.

[1] Cal/EPA contacts: WEBSITE www.cdpr.ca.gov or Main Information Center (916) 324-0419.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1680, Business and Professions Code.

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MEMORANDUM

DATE	October 26, 2010
TO	Dental Board Members Dental Board of California
FROM	Sarah Wallace Legislative & Regulatory Analyst
SUBJECT	**Agenda Item 5 (A):** Discussion and Possible Action to Consider Comments Received During the 15-Day Modified Text Notice Comment Period Relative to Proposed Amendments to Title 16, CCR, Sections 1070, 1070.1, 1070.2, 1071, and Proposed Additions to Title 16, CCR, Section 1070.6, 1070.7, 1070.8 for Dental Assisting Educational Programs and Courses

Background

Assembly Bill 2637 was passed by the Legislature and signed into law on September 28, 2008. The provisions of this bill relate to the allowable duties and settings for dental assistants, Registered Dental Assistants (RDA), Registered Dental Assistants in Extended Functions (RDAEF) and the two new permit categories for Orthodontic Assistant (OA) and Dental Sedation Assistant (DSA) become effective on January 1, 2010. AB 2637 included an expiration date on the Sections of law pertaining to educational program and course approvals, with the understanding that regulations would be pursued to clarify specific standards and criteria that these programs and course must meet to obtain Board approval to teach newly allowed duties and conform to the statutory changes.

The Board adopted proposed regulatory language at the November 2009 meeting. The proposed regulatory language regarding Dental Assisting Educational Programs and Courses was noticed on the Board's website and mailed on June 4, 2010 for the 45-day comment period. The comment period began on June 4, 2010 and ended on July 19, 2010. The regulatory hearing was held on July 19, 2010.

At the September 16, 2010 meeting, the Board reviewed comments received during the 45-day public comment period. The board voted to modify the text and notice it for 15-day modified text public comment period. The public comment period began on September 28, 2010 and ended on October 12, 2010. Comments were received from the following organizations:

- Butte Sierra District Dental Society
- Dental Assisting Alliance

- California Dental Association
- California Association of Dental Assisting Teachers

Board Action Requested

The Board may take action to reject or accept any comments. A rationale must be provided for any comments that are rejected. If comments are accepted, and the regulatory language is modified, the second modified text must be noticed for a 15-day public comment period, and any negative comments received during that time must be brought back to the Board for a response.

STAFF RECOMMENDATIONS FOR RESPONSE TO COMMENTS RECEIVED DURING THE 15-DAY PUBLIC COMMENT PERIOD REGARDING THE MODIFIED TEXT FOR DENTAL ASSISTING EDUCATIONAL PROGRAMS AND COURSES, CALIFORNIA CODE OF REGULATIONS, SECTIONS 1070, 1070.1, 1070.2, 1070.6, 1070.7, 1070.8, AND 1071

COMMENTS RECEIVED FROM BUTTE SIERRA DISTRICT DENTAL SOCIETY:

Butte Sierra District Dental Society commented that the terminology proposed in Section 1070.2(d)(9)(D) pertaining to basic life support course would cause confusion with the continuing education regulations for licensees. They also commented that the Board would be put in the position of approving Basic Life Support programs other than the American Heart Association or American Red Cross providers.

Staff recommends rejection of this comment. The board's continuing education requirements are not germane to the approval of Registered Dental Assistant programs. Each program application is reviewed individually. The board may review the programs' basic life support course and instructor and determine if the course is equivalent during the initial application review.

COMMENTS RECEIVED FROM THE DENTAL ASSISTING ALLIANCE:

Comment 1:

The Dental Assisting Alliance provided the following comment:

> **1070.8. Approval of Dental Sedation Assistant Permit Courses**
> **Subsection (a)(1),(2), and (3) – Faculty and Clinical Instruction Requirements.**
> In subdivisions (1), (2), and (3) of subsection (a), the term "designated faculty member" has been added. It is unclear what this term means. It would seem that a person is either a faculty member or they are not. While the term "designated faculty member" has been used in another part of the regulatory package regarding externships, it was used to indicate that the course director can designate certain duties to a faculty member with regard to oversight of extern sites. There appears no similar purpose for the use of the term within this context.

Staff recommends rejection of this comment. The term "designated faculty member" is applicable to this subsection. The term specifies the designated person responsible for clinical evaluation during the dental sedation assistant permit course.

Comment 2:
The Dental Assisting Alliance provided the following comment:

> **1070.8. Approval of Dental Sedation Assistant Permit Courses**
> **Subsection (b) – Clinical Instruction**
> The following section is proposed by the Board to be added at the end of subsection (b):
> (b)....Clinical instruction shall require completion of the duties described in Section 1750.5 of the Code during no less than twenty (20) supervised cases utilizing conscious sedation or general anesthesia.
>
> It is unclear whether this section specifically requires that the 20 cases include EACH of the duties described in Section 1750.5 of the Code. Since specific numbers of clinical experiences for each procedure have been proposed to be eliminated in later subdivisions (see (j)(3), (k)(3), (l)(3), (m)(3), and (n)(3)), we believe it is important for the public health and safety to clarify the above statement to assure that all providers are required to complete the same specific numbers of clinical experiences for each procedure that requires completion of clinical instruction. We recommend that the section be amended as follows:
>
> (b)....Clinical instruction shall require completion of **all of** the duties described in Section 1750.5 of the Code during no less than twenty (20) supervised cases utilizing conscious sedation or general anesthesia.

Staff recommends acceptance of this comment.

Comment 3:
The Dental Assisting Alliance provided the following comment:

> **1070.8. Approval of Dental Sedation Assistant Permit Courses**
> ***Subsections (f)(2), (j)(2), (k)(2), (l)(2), (m)(2), and (n)(2) – Pre-Clinical Instruction***
> It is unclear why the specified required number of pre-clinical experiences are proposed by the Board to be deleted, and language added that essentially allows the course provider to determine proficiency at any point in time. (Subsections (f)(2), (j)(2), (k)(2), (l)(2), (m)(2), and (n)(2)).
>
> The proposed regulations for Infection Control courses, Orthodontic Assistant courses, and EF educational programs all contain specific numbers of pre-clinical experiences that must be completed prior to a student's performance of such procedures on patients. It is therefore unclear why it is proposed that this course be regulated differently. Since individuals who complete this course are not required to be examined clinically by the state, it is even more important for public health and safety that minimum numbers be established to assure that providers don't simply require one experience for each procedure.
>
> We therefore recommend that subdivisions (f)(2), (j)(2), (k)(2), (l)(2), (m)(2), and (n)(2) be amended to re-instate the specific numbers of pre-clinical experiences that existed in the

prior version of the proposed regulation.

Staff recommends rejection of this comment. In order to promote better public protection in regards to sedation, it is pertinent that the student be able to demonstrate proficiency during laboratory and preclinical instruction rather than complete a specified number of experience. The requirements for demonstration of proficiency provided in section 1070(i) indicate that "objective evaluation criteria shall be used". All programs and courses are required to provide students with specific performance objectives, defined standards of performance, and those steps that would cause the student to fail the task being evaluated, all of which are reviewed by the Board during the application review process. This is the true measure of proficiency, not the number of times a task is performed.

Comment 4:

The Dental Assisting Alliance provided the following comment:

> **1071.1. Requirements for Approval of RDAEF Educational Programs**
> ***Subsections (b)(2)(A) and (e) – Program Hours and Clinical Instruction***
> The current language proposes hours based on the content contained in current law. However, the proposed regulations include revisions to require additional simulated clinical instruction for fitting, and cementing master and accessory points, additional clinical instruction for direct restorations, and additional clinical instruction for adjusting and cementing permanent indirect restorations.
>
> It is important that the program hours be increased to reflect whatever additional requirements are ultimately determined by the Board to be necessary.
>
> The hours and requirements in current statute were carefully calculated when AB2637 was drafted to assure that students would be minimally qualified upon graduation. According to feedback from existing programs, the current minimum number of hours is barely sufficient to appropriately instruct in all of the EF duties.
>
> Revising the minimum number of hours will ensure that each program will provide a minimum number of hours that are realistic and truly assure that each student achieves competence in each of the allowable duties. It also assists Board staff and/or consultants in evaluating each program in a fair and consistent manner.
>
> All other dental assisting programs and courses contain realistic minimum numbers of required hours. Treating EF programs differently will allow unscrupulous providers to provide all required instruction within an unrealistic minimum number of hours, which are not sufficient for students to achieve competence in each duty.
>
> Based on the proposed addition of 22 direct restorations, the proposed 4 simulated endo experiences, and our proposed 2 indirect restorations, we are proposing that the minimum program hours be changed by adding 58 hours, calculated as follows: 4 simulated endo x 2 hours each = 8 additional laboratory hours; 22 direct restorations x 2 hours each = 44 additional clinical hours; and 2 indirect restorations x 3 hours each = 6 additional clinical hours.

We therefore recommend that subsection (b)(2)(A), which governs EF programs for existing EFs, be amended to change the total minimum program hours from 288 to 346, leave the didactic hours at 76, change the laboratory hours from 180 to 188, and change the clinical hours from 32 to 82. As stated in other portions of the regulations, these clinical hours can be performed either within the facility, or at an extramural dental facility, or both.

We recommend that subsection (e), which governs EF programs for RDAs, be amended to change the total minimum program hours from 380 to 438, leave the didactic hours at 100, change the laboratory hours from 200 to 208, and change the clinical hours from 80 to 130.

Staff recommends acceptance of this comment with a few modifications. Based on the proposed addition of 22 direct restorations, the proposed 4 simulated endodontic experiences, and the Dental Assisting Alliance's proposed 2 indirect restorations, staff proposes that the minimum program hours be changed by adding 32 hours, calculated as follows:

- 4 simulated endodontic experiences x 1.5 hours each = 6 additional laboratory hours;
- 22 direct restorations x 1 hours each = 22 additional clinical hours;
- and 2 indirect restorations x 2 hours each = 4 additional clinical hours.

To avoid duplication of training time, staff suggests the following language:

1071(b)(2)(A) The program shall be no less than ~~288~~ ***320*** hours, including at least 76 hours of didactic instruction, at least ~~180~~ ***186*** hours of laboratory instruction, and at least ~~32~~ ***58*** hours of clinical instruction.

1071 (~~d~~e) The program shall be of sufficient duration for the student to develop minimum competence in all of the duties that RDAEFs are authorized to perform, but in no event less than ~~380~~ ***412*** hours, including at least 100 hours of didactic instruction, at least ~~200~~ ***206*** hours of laboratory instruction, and at least ~~80~~ ***106*** hours of clinical instruction. All laboratory and simulated clinical instruction shall be provided under the direct supervision of program staff. Clinical instruction shall be provided under the direct supervision of a licensed dentist and may be completed in an extramural dental facility as defined in Section 1070.1(i).

Comment 5:
The Dental Assisting Alliance provided the following comment:

1071.1. Requirements for Approval of RDAEF Educational Programs
Subsection (m)(4) – Placing, Contouring, Finishing, and Adjusting Direct Restorations

The Alliance supports the addition of direct restorations in a clinical setting, but we believe that the types of restorations should be revised to reflect current practice, and for public health and safety.

Based on statistics from all over the state, and the country, less than 50% of all types of

dental practices still use amalgam as a restorative material. That number is expected to continue to drop over the next few years. Forcing individuals to use materials that are no longer being widely used is contrary to educational standards, particularly in view of the rapid change in dental restorative materials. Most importantly, forcing patients to have restorations from materials they may not wish is contrary to appropriate patient care. Therefore, we recommend that subsection (m)(4) be amended to read as follows. We have not included
Class I restorations, since an individual who can successfully place a Class II restoration can easily place a Class I restoration.

(4) Clinical instruction shall include experience with the following techniques, at least fifty percent of which must utilize esthetic restorative materials, and at least ten percent of which must utilize amalgam:

(A) Placement of a Class II restoration in ten prepared permanent teeth;
(B) Placement of a Class V restoration in two prepared permanent teeth; and,
(C) Placement of a Class III or IV restoration in ten prepared permanent teeth.

Staff recommends rejection of this proposed language modification. Staff agrees that they Dental Assisting Alliance provided a good recommendation to require 50% of the clinical experiences utilize esthetic restorative material, and at least 10% of the clinical experiences utilize amalgam. However, the manner in which the language is written does not allow for flexibility for the programs to add experiences in certain classes without proportionally adjusting the experiences in other classes. The recommended language also requires experiences in Class IV restorations which is not a listed duty.

Comment 6:
The Dental Assisting Alliance provided the following comment:

1071.1. Requirements for Approval of RDAEF Educational Programs
Subdivision (o) – Adjusting and Cementing Permanent Indirect Restorations
In subdivision(o)(2)(B), it is proposed that students must complete laboratory experience consisting of placing indirect restorations on one anterior and one posterior tooth for each of the following materials: ceramic, ceramometal, and cast metal. It is not appropriate for students to place cast metal crowns on anterior teeth, as this is not done in practice. Since the techniques for adjusting and cementing ceramic, ceramometal, and cast metal permanent crowns are essentially identical, we recommend that the subsection be amended to eliminate the specificity about the types of crowns which must be placed:

(B) Fitting, adjusting, and cementation of permanent indirect restorations on three anterior teeth and three posterior teeth.

In subdivision (o)(4), it is proposed that students be required to complete the placement of six indirect restorations on patients.

We believe that this requirement is excessive, and that the types of crowns do not need to be specified, since the techniques for each type are identical. In addition, as with (o)(2)(B) above, it is inappropriate to place cast metal restorations on anterior teeth, as proposed. Therefore, we recommend that the section be amended to read as follows:

(4) Clinical instruction shall include fitting, adjustment, and cementation of permanent indirect restorations on at least two teeth.

Staff recommends acceptance of this comment.

COMMENTS RECEIVED FROM THE CALIFORNIA DENTAL ASSOCIATION

Comment 1:

The California Dental Association provided the following comment:

Section 1071(m)(4) – RDAEF clinical instruction for direct restorations

The workgroup carefully considered the proposed instructional changes for the RDAEF duty of placing, contouring and finishing direct restorations and agreed with the Board's recommendation to require formal clinical training. Clinical instruction provides the opportunity to reasonably assess the student's ability to translate the skills they mastered to proficiency in a simulated setting to the intraoral environment of a live patient.

CDA recommends the majority of clinical instruction include the classes of restorations and materials that are most difficult: Class II and Class V restorations using esthetic materials. If a student can complete these most difficult restorations to proficiency, it is reasonable to assume that he or she can complete a more basic restoration using the same sets of skills. Acknowledging that the restorative skills are learned and mastered in the simulated clinical settings, there is no sufficient value, and in fact it would be a barrier to require more extensive, repetitive clinical hours or to require clinical instruction in all classes of restoration with every material.

While the majority of clinical instruction should demonstrate experience with esthetic materials, CDA recommends that at least some of the required instruction include amalgam restorations because the skills required for placing, contouring and finishing amalgam are different than those required for esthetic materials.

CDA proposes the following changes to the proposed regulations:

(4) Clinical instruction shall ~~include experience with the following techniques~~ require proficient completion of placing, contouring and finishing at least twenty (20) direct restorations in prepared permanent teeth with the following requirements.

~~(A) Placement of Class I, II, and V amalgam restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.~~

~~*(B) Placement of Class I, II, III, and V composite resin restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.*~~

~~*(C) Placement of Class I, II, III, and V glass-ionomer restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.*~~

(A) At least fifty (50) percent of the experiences shall be Class II restorations using esthetic materials.

(B) At least twenty (20) percent of the experiences shall be Class V restorations using esthetic materials.

(C) At least ten (10) percent of the experiences shall use amalgam.

Staff recommends acceptance of this comment with the addition of new subdivision (4)(D) stating:

(D) Students who complete the 20 restorations and meet all the instructional requirements of this section may complete additional Class I,II,III or V restorations as deemed appropriate for program success.

Comment 2:

The California Dental Association provided the following comment:

Section 1071(o)(4) – RDAEF clinical instruction for permanent indirect restorations
CDA does not agree that it is necessary to require clinical instruction with respect to the RDAEF duty of adjusting and cementing permanent indirect restorations. Performing this duty in a live-patient, intraoral setting does not demonstrate any additional proficiency of the required skills beyond the simulated clinical setting and is easily reversible if required. CDA recommends deleting this clinical requirement.

CDA proposes the following changes to the proposed regulations:

~~*(4) Clinical instruction shall include fitting, adjustment, and cementation of permanent indirect restorations on at least one anterior and one posterior tooth for each of the following materials, with one of each type used for a clinical examination: ceramic, ceramometal, and cast metallic.*~~

Staff recommends rejection of this comment. Protection of the public is the board's highest priority. It is imperative that Registered Dental Assistants in Extended Functions have the appropriate clinical training before practicing on patients.

Comment 3:

The California Dental Association provided the following comment:

Section 1070(j) – Definition of "extramural dental facility"
CDA recommends changing the definition of "extramural dental facility" to clarify that an "approved" dental assisting educational program means a board-approved program. Additionally, CDA recommends adding clarifying language to the definition to ensure there

is not confusion that the primary location of a dental assisting educational program may be a clinical facility.

CDA proposes the following changes to the proposed regulations:

(ij) (1) As used in this article "extramural dental facility" means any clinical facility employed by ~~an~~ board-approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary ~~campus~~ location of the board-approved program and in which dental treatment is rendered. Nothing in this definition shall exclude a dental office or dental clinic from being the primary location of a board-approved program.

Staff recommends partial acceptance of the California Dental Association's comment. Staff recommends accepting the addition of "board-approved" and changing "campus" to "location".

Staff recommends rejecting the recommendation to add "Nothing in this definition shall exclude a dental office or dental clinic from being the primary location of a board-approved program." The addition of this sentence is not germane to the definition. There is nothing in this regulation that would preclude a dental office or dental clinic from being the primary location of a program as long as the qualifications are met.

Comment 4:
The California Dental Association provided the following comment:

Section 1070.2 (d) (11) – RDA program general didactic instruction
CDA recommends the following clarifying and technical modifications to the original text in this section:

a. Change "Principles of..." to "Overview of..." in all subsections.
b. In subsection (L), change "preventative" to "preventive"
c. In subsection (L), add the term "caries risk assessment" between "including," and "plaque identification".

CDA proposes the following changes to the proposed regulations:

(L) ~~Principles~~ Overview of and protocols for oral hygiene preventative methods including, caries risk assessment, plaque identification, toothbrushing and flossing techniques, and nutrition.

Staff recommends rejection of this comment. Changing the term "principle" to "overview" insinuates teaching a general idea or summary. By keeping the term "principle", the language establishes that standards are to be taught. Changing the term "preventative" to "preventive" is unnecessary as the two terms are synonymous. It is unnecessary to include "caries risk assessment" as it is a basic supportive duty that falls within the duties for a dental assistant as described in Business and Professions Code Section 1750. A "caries risk assessment" involves filling out a questionnaire, and according to American Academy of Pediatric Dentistry guidelines, may be performed by clinical or non-clinical

personnel. It is an assessment and not a diagnosis, is completely reversible, and is unlikely to precipitate potentially hazardous conditions for the patient being treated.

COMMENTS RECEIVED FROM THE CALIFORNIA ASSOCIATION OF DENTAL ASSISTING TEACHERS

Comment 1:
The California Association of Dental Assisting Teachers provided the following comment:

> ***Amend the name of the Notice:***
> ***As noticed:*** Notice of Compliance with New Requirements for Registered Dental Assistant ~~Educational~~ Programs and Dental Assisting Educational Courses
>
> *Rationale: Section 1070 of the modified text pertains to all dental assistant educational programs and courses and as such the form may be utilized by the Board staff to address compliance issues of both programs and course providers. Amending the Notice title allows for the staff to utilize the form when accessing RDA programs as well as OAP and DSAP permit courses and educational courses for certification.*

Staff recommends rejection of this comment. The "Notice of Compliance with New Requirements for Registered Dental Assistant Programs" New (09/10) is specific to the section pertaining to Registered Dental Assistant Programs. The proposed additions are not relevant to section 1070.2 regarding Registered Dental Assistant Educational Programs.

However, staff recommends modifying the text to include new forms for notice of compliance for the infection control courses, dental sedation assistant permit courses, orthodontic assistant permit courses, and the Registered Dental Assistant in Extended Functions Programs. Staff recommends the addition of the following language to incorporate the new forms:

> **1070.6. Approval of Infection Control Courses**
> ***(h) 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 Infection Control Courses (New 10/10)" within ninety (90) days of the effective date of these regulations.***
>
> **1070.7. Approval of Orthodontic Assistant Permit Courses**
> ***(l) 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 Orthodontic Assistant Permit Courses (New 10/10)" within ninety (90) days of the effective date of these regulations.***
>
> **1070.8. Approval of Dental Sedation Assistant Permit Courses**
> ***(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)" within ninety (90) days of the effective date of these regulations.***

Section 1071. Approval of RDAEF Educational Programs.
(q) 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 Registered Dental Assistant in Extended Functions Educational Programs (New 10/10)" within ninety (90) days of the effective date of these regulations.

Comment 2:
The California Association of Dental Assisting Teachers provided the following comment:

Amend the opening statement of the Notice:
As noticed: To maintain approval by the Board, ~~each~~ Registered Dental Assistant (RDA) programs and dental assisting educational courses ~~that was~~ approved prior to the date that Sections 1070, 1070.1 and 1070.2 became effective, must complete and submit this form and submit to the Board at its offices no later than 90 days from the effective date of these new requirements. Any student graduating from such a program or course will not be accepted to sit for examination or qualify for registration until this ~~form~~ Notice has been submitted to the Board. Certificates of Completion issued by educational course providers not meeting Notice submission requirements will not be recognized by the Board.

Rationale: Modified text Sections 1070, 1070.1 and 1070.2 all pertain to program and course providers and as such should be referenced in the above statement. Each Section includes both programs and course providers and should be reflected in the language as to all whom this Notice applies. Not all educational courses require State-administered examinations upon course completion and as such the Certificate of Course Completion issued by the course provider should be referenced as being invalid in the event the course provider does not meet the Notice requirements.

Staff recommends rejection of this comment. The "Notice of Compliance with New Requirements for Registered Dental Assistant Programs" New (09/10) is specific to the section pertaining to Registered Dental Assistant Programs. The proposed additions are not relevant to section 1070.2 regarding Registered Dental Assistant Educational Programs.

However, staff recommended modifying the text to include new forms for notice of compliance for the infection control courses, dental sedation assistant permit courses, orthodontic assistant permit courses, and the Registered Dental Assistant in Extended Functions Programs. Staff recommends using CADAT's recommended changes in the new forms for the courses' notice of compliance.

Comment 3:
The California Association of Dental Assisting Teachers provided the following comment:

Amend certifying statements on the Notice:
As noticed:

(1) I have read the attached regulations pertaining to ~~the approval of Registered Dental Assistant (RDA)~~ all dental assisting educational programs and courses, including Sections 1070, 1070.1 and 1070.2 of Title 16 of the California Code of Regulations;
(2) I have the authority to sign this Notice on behalf of the educational institution ~~or~~, program or course provider; and,
(3) That to the best of my knowledge, information and belief, the institution, organization or private course provider and its programs or courses for which I am responsible or duly authorized to represent complies with these regulations and can demonstrate to the Board having been in compliance with these regulations since _____(insert date).

Rationale: As previously cited, Section 1070.1 is also applicable to the Notice requirements. Not all programs or courses are offered by institutional providers and as such approved organizations and private providers should be referenced in the Notice. Given that the educational regulations provide for the Board to exercise its right to site visit a program or course provider, we believe the certifying statement should address the program or courses ability to show proof of compliance at the request of the Board at any time, and that the certifying party should be made aware of such responsibility prior to signature.

Staff recommends rejection of this comment. The "Notice of Compliance with New Requirements for Registered Dental Assistant Programs" New (09/10) is specific to the section pertaining to Registered Dental Assistant Programs. The proposed additions are not relevant to section 1070.2 regarding Registered Dental Assistant Educational Programs.

However, staff recommends using some of CADAT's recommended language in the development of the notice of compliance for the infection control course, the dental sedation assistant permit course, and the orthodonitic assistant permit course:

Certifying statements on the Notice of Compliance for Infection Control Courses:
(1) I have read the attached regulations pertaining to the approval of Infection Control Courses, including Sections 1070, 1070.1 and 1070.6 of Title 16 of the California Code of Regulations;
(2) I have the authority to sign this notice on behalf of the educational institution, organization, or course provider; and,
(3) That to the best of my knowledge, information and belief, the institution, organization or course provider and its programs or courses comply with these regulations and have been in compliance with these regulations since _____(insert date).

Certifying statements on the Notice of Compliance for Orthodontic Assistant Permit Courses:
(1) I have read the attached regulations pertaining to the approval of Orthodontic Assistant Permit Courses, including Sections 1070, 1070.1 and 1070.7 of Title 16 of the California Code of Regulations;

(2) I have the authority to sign this notice on behalf of the educational institution, organization, or course provider; and,
(3) That to the best of my knowledge, information and belief, the institution, organization or course provider and its programs or courses comply with these regulations and have been in compliance with these regulations since _____(insert date).

Certifying statements on the Notice of Compliance for Dental Sedation Assistant Permit Courses:
(1) I have read the attached regulations pertaining to the approval of Dental Sedation Assistant Permit Courses, including Sections 1070, 1070.1 and 1070.8 of Title 16 of the California Code of Regulations;
(2) I have the authority to sign this notice on behalf of the educational institution, organization, or course provider; and,
(3) That to the best of my knowledge, information and belief, the institution, organization or course provider and its programs or courses comply with these regulations and have been in compliance with these regulations since _____(insert date).

Comment 4:
The California Association of Dental Assisting Teachers provided the following comment:

Amend Notice to include verification of faculty or instructional staff and current Program Director:
CADAT is concerned about the lack of accurate staff information reported to the Board for all educational programs and courses. By including a verification table for the responsible party to submit demonstrating the current faculty, instructors and Directors, the Board will have the data necessary to ensure that those teaching courses are meeting the educational requirements and licensure/permit status to teach specific subject areas.

Staff recommends rejection of this comment. It is unnecessary for the programs or courses to provide a verification of faculty or instructional staff with a notice of compliance. The programs and courses include this information in the initial application and they are required to notify the board of any changes in faculty or instructional staff within 10 days.

ADDITIONAL RECOMMENDATIONS FROM THE BOARD'S SUBCOMMITTEE:

Subcommittee Recommendation #1:

The subcommittee recommended the following modified language in order to relieve the burden from the RDA programs of having to own a CAD machine or capnograph. This provides the RDA programs the flexibility to provide training using costly equipment by alternative means such as simulated devices. This is most often done by using outside providers who own this equipment.

> (A) The following are minimum requirements for equipment and armamentaria during laboratory, preclinical, and clinical sessions as appropriate to each type of session: amalgamator, model trimmers in the ratio of one for every seven students, dental rotary equipment in the ratio of one for every three students, vibrators in the ratio of one for every three students, light curing devices in the ratio of one for every operatory, functional typodonts and bench mounts in the ratio of one for every two students, functional orthodontically banded typodonts in the ratio of one for every four students, facebows in the ratio of one for every ten students, automated blood pressure device, EKG machine, pulse oximeters in the ratio of one for every ten students, capnograph or simulated device, one sets of hand instruments in the ratio of one set for every two students for each procedure, respiration device, camera for intraoral use, camera for extraoral use, CAD machine or simulated device, caries detection device in the ratio of one for every ten students, and all other equipment and armamentaria required to teach dental assistant and registered dental assistant duties. With the exception of ***a CAD machine or*** patient monitoring equipment specific to EKG machine, ~~***and***~~ pulse oximeter, ***and capnograph*** the program shall own the necessary equipment and have it readily available upon inspection. Patient monitoring equipment owned by the institution and utilized by more than one program within the institution premises is acceptable and may be used by the RDA program as needed for instruction. Instruction by a licensed healthcare provider is acceptable. In the event instruction in patient monitoring procedures ***and use of the CAD machine*** is provided by an outside provider, the RDA program shall not be required to have available or own patient monitoring equipment ***or CAD machine***.

Subcommittee Recommendation #2:

The subcommittee recommended the following modified language in section 1070.8(a)(3) relating to clinical instruction supervision for the Dental Sedation Assistant Permit Course. Business and Professions Code Section 1750.5 requires the dentist or other licensed health care professional to be at the patient's chair-side while conscious sedation or general anesthesia is being administered. To maintain public protection it is necessary for the director, designated faculty member, or instructional staff member authorized to administer conscious sedation or general anesthesia to be at the patient's chair-side during clinical instruction.

> (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 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 sedation or general anesthesia.***

who shall be at the patient's chairside while conscious sedation or general anesthesia is being administered.

Subcommittee Recommendation #3:

The subcommittee recommends the following modified language to clarify that the clinical instruction will require completion of all of the task described in subdivisions (j), (k), (l), (m), and (n) of section 1070.8. This helps to specify what tasks are required by the regulation rather than the Statute. The statute has a much broader definition and the proposed regulations have specified the requirements.

(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 ~~***duties***~~ ***tasks*** described in ~~***Section 1750.5 of the Code***~~ ***subdivisions (j), (k), (l), (m), and (n) of this Section*** during no less than twenty (20) supervised cases utilizing conscious sedation or general anesthesia.

Subcommittee Recommendation #4:

The subcommittee recommends striking "Board-approved" from section 1071(d), pertaining to the educational methodology course or certification program requirements for faculty members responsible for clinical evaluation. The subcommittee made this recommendation to maintain consistency between the requirements for the RDA programs and the RDAEF programs. The following language is suggested:

(~~c~~d) ~~Adequate provision for the supervision and operation of the program shall be made in compliance with section 1070. Notwithstanding the requirements of Sections 1070 and 1070.1, the program director and each faculty member of an approved RDAEF program shall possess a valid, active, and current license as a dentist or an RDAEF.~~ In addition to the requirements of Sections 1070 and 1070.1, all faculty members responsible for clinical evaluation shall have completed a ~~six-hour teaching methodology course in clinical evaluation prior to conducting clinical evaluations of students~~ ***Board-approved*** course or certification program in educational methodology of at least six (6) hours by January 1, 2012, unless he or she holds any one of the following: a postgraduate degree in education, a Ryan Designated Subjects Vocational Education Teaching Credential, a Standard Designated Subjects Teaching Credential, or, a Community College Teaching Credential. Each faculty member employed on or after January 1, 2012, shall complete a course or certification program in educational methodology within six months of employment. The program director or designated administrator shall be responsible to obtain and maintain records of each faculty member showing evidence of having met this regulation.

Subcommittee Recommendation #5:

The subcommittee recommended modifying the text of section 1071(j) to maintain consistency with the terminology of "master points" and "accessory points". The following language modifications are recommended:

(i~~j~~) With respect to sizing, fitting, and cementing endodontic master points and accessory points:

(1) Didactic instruction shall include the following:

(A) Review of objectives, canal preparation, filling of root canal space, including the role of the RDAEF as preparatory to condensation which is to be performed by the licensed dentist.

(B) Description and goals of filling technique using lateral condensation techniques.

(C) Principles and techniques of fitting, ***and*** cementing master ***points*** and accessory points using lateral condensation including, characteristics, manipulation, use of gutta percha and related materials, and criteria for an acceptable master and accessory points technique using lateral condensation.

(2) Laboratory instruction shall include fitting ***and cementing*** master ***points and accessory points*** ~~***and cementing cones***~~ on extracted teeth or ~~assimilated~~ simulated teeth with canals in preparation for lateral condensation by the dentist, with at a minimum two experiences each on a posterior and anterior tooth. This instruction shall not include obturator based techniques or other techniques that employ condensation.

(3) Simulated clinical instruction shall include fitting, ***and*** cementing master ***points*** and accessory points in preparation for condensation by the dentist with extracted or simulated teeth prepared for lateral condensation mounted in simulated patient heads mounted in appropriate position and accommodating and articulated typodont in an enclosed intraoral environment, or mounted on a dental chair in a dental operatory. This instruction shall not include obturator based techniques that employ condensation. Simulated clinical instruction shall include fitting ***and cementing*** master ***points*** ~~***cones***~~ and accessory points for lateral condensation by the dentist in at least four teeth, one of which shall be used for a practical exam.

Dental Assisting ALLIANCE

California Dental Assistants Association (CDAA)
Expanded Functions Dental Assistants Association (EFDAA)

October 10, 2010

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

RE: **Alliance Comments on Proposed Regulations 1070, 1070.1, 1070.2, 1070.6, 1070.7, 1070.8, and 1071**

Following are the comments of the Alliance regarding the above-referenced proposed regulations.

1070.8. Approval of Dental Sedation Assistant Permit Courses

Subsection (a)(1),(2), and (3) – Faculty and Clinical Instruction Requirements.

In subdivisions (1), (2), and (3) of subsection (a), the term "designated faculty member" has been added. It is unclear what this term means. It would seem that a person is either a faculty member or they are not. While the term "designated faculty member" has been used in another part of the regulatory package regarding externships, it was used to indicate that the course director can designate certain duties to a faculty member with regard to oversight of extern sites. There appears no similar purpose for the use of the term within this context.

Subsection (b) – Clinical Instruction

The following section is proposed by the Board to be added at the end of subsection (b):

(b)....Clinical instruction shall require completion of the duties described in Section 1750.5 of the Code during no less than twenty (20) supervised cases utilizing conscious sedation or general anesthesia.

It is unclear whether this section specifically requires that the 20 cases include EACH of the duties described in Section 1750.5 of the Code. Since specific numbers of clinical experiences for each procedure have been proposed to be eliminated in later subdivisions (see (j)(3), (k)(3), (l)(3), (m)(3), and (n)(3)), we believe it is important for the public health and safety to clarify the above statement to assure that all providers are required to complete the same specific numbers of clinical experiences for each procedure that requires completion of clinical instruction. We recommend that the section be amended as follows:

(b)....Clinical instruction shall require completion of **all of** the duties described in Section 1750.5 of the Code during no less than twenty (20) supervised cases utilizing conscious sedation or general anesthesia.

Subsections (f)(2), (j)(2), (k)(2), (l)(2), (m)(2), and (n)(2) – Pre-Clinical Instruction

It is unclear why the specified required number of pre-clinical experiences are proposed by the Board to be deleted, and language added that essentially allows the course provider to determine proficiency at any point in time. (Subsections (f)(2), (j)(2), (k)(2), (l)(2), (m)(2), and (n)(2)).

The proposed regulations for Infection Control courses, Orthodontic Assistant courses, and EF educational programs all contain specific numbers of pre-clinical experiences that must be completed prior to a student's performance of such procedures on patients. It is therefore unclear why it is proposed that this course be regulated differently. Since individuals who complete this course are not required to be examined clinically by the state, it is even more important for public health and safety that minimum numbers be established to assure that providers don't simply require one experience for each procedure.

We therefore recommend that subdivisions (f)(2), (j)(2), (k)(2), (l)(2), (m)(2), and (n)(2) be amended to re-instate the specific numbers of pre-clinical experiences that existed in the prior version of the proposed regulation.

1071.1. Requirements for Approval of RDAEF Educational Programs

Subsections (b)(2)(A) and (e) – Program Hours and Clinical Instruction

The current language proposes hours based on the content contained in current law. However, the proposed regulations include revisions to require additional simulated clinical instruction for fitting, and cementing master and accessory points, additional clinical instruction for direct restorations, and additional clinical instruction for adjusting and cementing permanent indirect restorations.

It is important that the program hours be increased to reflect whatever additional requirements are ultimately determined by the Board to be necessary.

The hours and requirements in current statute were carefully calculated when AB2637 was drafted to assure that students would be minimally qualified upon graduation. According to feedback from existing programs, the current minimum number of hours is barely sufficient to appropriately instruct in all of the EF duties.

Revising the minimum number of hours will ensure that each program will provide a minimum number of hours that are realistic and truly assure that each student achieves competence in each of the allowable duties. It also assists Board staff and/or consultants in evaluating each program in a fair and consistent manner.

All other dental assisting programs and courses contain realistic minimum numbers of required hours. Treating EF programs differently will allow unscrupulous providers to provide all required instruction within an unrealistic minimum number of hours, which are not sufficient for students to achieve competence in each duty.

Based on the proposed addition of 22 direct restorations, the proposed 4 simulated endo experiences, and our proposed 2 indirect restorations, we are proposing that the minimum program hours be changed by adding 58 hours, calculated as follows: 4 simulated endo x 2 hours each = 8 additional laboratory hours; 22 direct restorations x 2 hours each = 44 additional clinical hours; and 2 indirect restorations x 3 hours each = 6 additional clinical hours.

We therefore recommend that subsection (b)(2)(A), which governs EF programs for existing EFs, be amended to change the total minimum program hours from 288 to 346, leave the didactic hours at 76, change the laboratory hours from 180 to 188, and change the clinical hours from 32 to 82. As stated in other portions of the regulations, these clinical hours can be performed either within the facility, or at an extramural dental facility, or both.

We recommend that subsection (e), which governs EF programs for RDAs, be amended to change the total minimum program hours from 380 to 438, leave the didactic hours at 100, change the laboratory hours from 200 to 208, and change the clinical hours from 80 to 130.

Subsection (m)(4) – Placing, Contouring, Finishing, and Adjusting Direct Restorations

The Alliance supports the addition of direct restorations in a clinical setting, but we believe that the types of restorations should be revised to reflect current practice, and for public health and safety.

Based on statistics from all over the state, and the country, less than 50% of all types of dental practices still use amalgam as a restorative material. That number is expected to continue to drop over the next few years. Forcing individuals to use materials that are no longer being widely used is contrary to educational standards, particularly in view of the rapid change in dental restorative materials. Most importantly, forcing patients to have restorations from materials they may not wish is contrary to appropriate patient care.

Therefore, we recommend that subsection (m)(4) be amended to read as follows. We have not included Class I restorations, since an individual who can successfully place a Class II restoration can easily place a Class I restoration.

> (4) Clinical instruction shall include experience with the following techniques, at least fifty percent of which must utilize esthetic restorative materials, and at least ten percent of which must utilize amalgam:
> (A) Placement of a Class II restoration in ten prepared permanent teeth;
> (B) Placement of a Class V restoration in two prepared permanent teeth; and,
> (C) Placement of a Class III or IV restoration in ten prepared permanent teeth.

Subdivision (o) – Adjusting and Cementing Permanent Indirect Restorations

In subdivision(o)(2)(B), it is proposed that students must complete laboratory experience consisting of placing indirect restorations on one anterior and one posterior tooth for each of the following materials: ceramic, ceramometal, and cast metal. It is not appropriate for students to place cast metal crowns on anterior teeth, as this is not done in practice. Since the techniques for adjusting and cementing ceramic, ceramometal, and cast metal permanent crowns are essentially identical, we recommend that the subsection be amended to eliminate the specificity about the types of crowns which must be placed:

(B) Fitting, adjusting, and cementation of permanent indirect restorations on three anterior teeth and three posterior teeth.

In subdivision (o)(4), it is proposed that students be required to complete the placement of six indirect restorations on patients.

We believe that this requirement is excessive, and that the types of crowns do not need to be specified, since the techniques for each type are identical. In addition, as with (o)(2)(B) above, it is inappropriate to place cast metal restorations on anterior teeth, as proposed. Therefore, we recommend that the section be amended to read as follows:

(4) Clinical instruction shall include fitting, adjustment, and cementation of permanent indirect restorations on at least two teeth.

Sincerely,

Leslie Canham
Leslie Canham, RDA
Representing CDAA
(209) 785-3903

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October 11, 2010

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

Re: Proposed Dental Assisting Educational Programs and Courses Regulations Modified Text

Dear Dental Board Members:

The Butte Sierra District Dental Society (BSDDS) appreciates the opportunity to comment on the proposed modified text on the dental assisting educational programs that are under review by the Dental Board of California.

BSDDS offers the following comments based upon review of the proposed modified text:

Section 1070.2(b)(9)(D)

Suggested modified text is as follows:
(D) "A course in basic life support provided by an instructor approved by the American Red Cross or the American Heart Association, or any other course **approved by the Board** as equivalent. The program may require that the student complete this course as a prerequisite to program enrollment, or that the student provide evidence of having completed from another provider".

Licensees currently follow Title 16(b)(C)(i) and (ii)

"C) The mandatory requirement for certification in Basic Life Support shall be met by completion of either:

(i) An American Heart Association (AHA) or American Red Cross (ARC) course in Basic Life Support (BLS) or,

(ii) A BLS course taught by a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE).

For the purposes of this section, a Basic Life Support course shall include all of the following:

1. Instruction in both adult and pediatric CPR, including 2-rescuer scenarios;

2. Instruction in foreign-body airway obstruction;

3. Instruction in relief of choking for adults, child and infant;

4. Instruction in the use of automated external defibrillation with CPR; and;

5. A live, in-person skills practice session, a skills test and a written examination;

The course provider shall ensure that the course meets the required criteria."

If the terminology that is proposed in Section 1070.2(b)(9)(D) is adopted our concern is that licensed and unlicensed individuals alike would universally find this very confusing. It also appears that the verbiage in Section 1070.2(b)(9)(D) would also lend itself to The Dental Board finding itself in the position of approving or denying every Basic Life Support program other than an American Heart Association or American Red Cross provider.

We thank you for your consideration of these comments by BSDDS and look forward to any assistance we might be able to provide.

Sincerely,

Jeannie

Jeannie Pittman, CFR
Executive Director

Cc: Mr. Dean Chalios, CDA Vice President of Public Policy
Dr. Tom Pelton, CDA Trustee
Ms. Cathy Levering, SDDS Executive Director

October 12, 2010

Dental Board of California
Attn: Sarah Wallace, Legislative and Regulatory Analyst
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: Dental Assisting Educational Programs and Courses – Modified Text of Proposed Regulations

Dear Dental Board Members:

The California Dental Association (CDA) appreciates the opportunity to comment on the proposed dental assisting educational program and course regulations that are currently under consideration by the Dental Board of California. A workgroup of dentists was convened to review the proposed regulations and to prepare CDA's comments on the modified text. The workgroup consisted of general dentists, a dental educator, a pediatric dentist, and a dental clinic director. Based on the workgroup's review, CDA offers the following comments for the Board's consideration:

1. Section 1071(m)(4) – RDAEF clinical instruction for direct restorations

The workgroup carefully considered the proposed instructional changes for the RDAEF duty of placing, contouring and finishing direct restorations and agreed with the Board's recommendation to require formal clinical training. Clinical instruction provides the opportunity to reasonably assess the student's ability to translate the skills they mastered to proficiency in a simulated setting to the intraoral environment of a live patient.

CDA recommends the majority of clinical instruction include the classes of restorations and materials that are most difficult: Class II and Class V restorations using esthetic materials. If a student can complete these most difficult restorations to proficiency, it is reasonable to assume that he or she can complete a more basic restoration using the same sets of skills. Acknowledging that the restorative skills are learned and mastered in the simulated clinical settings, there is no sufficient value, and in fact it would be a barrier to require more extensive, repetitive clinical hours or to require clinical instruction in all classes of restoration with every material.

While the majority of clinical instruction should demonstrate experience with esthetic materials, CDA recommends that at least some of the required instruction include amalgam restorations because the skills required for placing, contouring and finishing amalgam are different than those required for esthetic materials.

CDA proposes the following changes to the proposed regulations:

(4) Clinical instruction shall ~~include experience with the following techniques~~ require proficient completion of placing, contouring and finishing at least twenty (20) direct restorations in prepared permanent teeth with the following requirements:

~~(A) Placement of Class I, II, and V amalgam restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.~~

~~(B) Placement of Class I, II, III, and V composite resin restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.~~

~~*(C) Placement of Class I, II, III, and V glass ionomer restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.*~~

(A) At least fifty (50) percent of the experiences shall be Class II restorations using esthetic materials.

(B) At least twenty (20) percent of the experiences shall be Class V restorations using esthetic materials.

(C) At least ten (10) percent of the experiences shall use amalgam.

2. Section 1071(o)(4) – RDAEF clinical instruction for permanent indirect restorations

CDA does not agree that it is necessary to require clinical instruction with respect to the RDAEF duty of adjusting and cementing permanent indirect restorations. Performing this duty in a live-patient, intraoral setting does not demonstrate any additional proficiency of the required skills beyond the simulated clinical setting and is easily reversible if required. CDA recommends deleting this clinical requirement.

CDA proposes the following changes to the proposed regulations:

~~*(4) Clinical instruction shall include fitting, adjustment, and cementation of permanent indirect restorations on at least one anterior and one posterior tooth for each of the following materials, with one of each type used for a clinical examination: ceramic, ceramometal, and cast metallic.*~~

3. Section 1070(j) – Definition of "extramural dental facility"

CDA recommends changing the definition of "extramural dental facility" to clarify that an "approved" dental assisting educational program means a board-approved program. Additionally, CDA recommends adding clarifying language to the definition to ensure there is not confusion that the primary location of a dental assisting educational program may be a clinical facility.

CDA proposes the following changes to the proposed regulations:

(ij) (1) As used in this article "extramural dental facility" means any clinical facility employed by ~~an~~ board-approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary ~~campus~~ location of the board-approved program and in which dental treatment is rendered. Nothing in this definition shall exclude a dental office or dental clinic from being the primary location of a board-approved program.

4. Section 1070.2 (d) (11) – RDA program general didactic instruction

CDA recommends the following clarifying and technical modifications to the original text in this section:

a. Change "Principles of…" to "Overview of…" in all subsections.
b. In subsection (L), change "preventative" to "preventive"
c. In subsection (L), add the term "caries risk assessment" between "including," and "plaque identification".

CDA proposes the following changes to the proposed regulations:

(L) ~~Principles~~ Overview of and protocols for oral hygiene preventative methods including, caries risk assessment, plaque identification, toothbrushing and flossing techniques, and nutrition.

Thank you for considering these changes. If you have any questions, please contact me at 916.554.4989 or dean.chalios@cda.org.

Sincerely,

Dean Chalios
Vice President, Public Policy

CADAT

October 4, 2010

Dr. John Bettinger, President
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: Notice of Modified Text - Educational Regulations to Implement AB2637

Dear Dr. Bettinger and Members of the Dental Board of California:

On behalf of the Board of Directors and membership of the California Association of Dental Assisting Teachers, we would like to express our appreciation for the Dental Board's recent action and creation of meaningful and supportive educational regulations for dental assisting programs and courses. We recognize the time-consuming and difficult process the Board members and the Board staff engaged in to ensure that the regulations provided the clarity and direction we as the course providers, institutional educators, deans and school administrators needed to fulfill our purpose. In doing so, you also provided the Board staff with the regulatory language needed to oversee, review, and develop new approval processes necessary for continued development of educational offerings in California.

It is our sincere hope that the approved educational regulations will continue to move forward without further delay. We foresee excellent opportunities in the future to work collaboratively with the Dental Assisting Subcommittee and the Board on new and innovative initiatives to enhance the examination candidate experience, create new credentialing opportunities, and consider new pathways to licensure.

In closing, please accept this letter of support from CADAT for the modified text dated September 27, 2010 pertaining to sections 1070, 1070.1, 1070.2, 1070.6, 1070.7, 1070.8, and 1071 of Division 10, Title 16 of the California Code of Regulations. Thank you again for your support and be assured that our representatives are available at any time to assist the Board and staff in matters of mutual interest regarding dental assisting education, examination and licensure.

Sincerely,

Lori Gagliardi, CDA, RDA, RDH, Ed.D.
Director – Policy Council

LaDonna Drury-Klein, CDA, RDA, BS
President

Tamara McNealy, RDA
Chair - Policy Council

Joy Myers, CDA, RDA, BS
Asst. Vice President/Policy Council

CADAT

October 12, 2010

Dr. John Bettinger, President
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: Notice of Compliance for Registered Dental Assistant Educational Programs

Dear Dr. Bettinger and Members of the Dental Board of California:

As part of the newly amended Dental Assisting Educational Regulations, modified text dated September 28, 2010, the Board developed the above stated Notice in an effort to provide Board-approved programs and courses with a mechanism to validate adherence to all educational regulations pertaining to dental assisting education. CADAT supported the creation of the proposed Notice of Compliance and would like to suggest amendments to the Notice in order to help garner more applicable data from the programs and courses.

We ask the Board to consider approving the following recommendations:

1. Amend the name of the Notice:
As noticed: Notice of Compliance with New Requirements for Registered Dental Assistant ~~Educational~~ Programs and Dental Assisting Educational Courses

Rationale: Section 1070 of the modified text pertains to all dental assistant educational programs and courses and as such the form may be utilized by the Board staff to address compliance issues of both programs and course providers. Amending the Notice title allows for the staff to utilize the form when accessing RDA programs as well as OAP and DSAP permit courses and educational courses for certification.

2. Amend the opening statement of the Notice:
As noticed: To maintain approval by the Board, ~~each~~ Registered Dental Assistant (RDA) programs and dental assisting educational courses ~~that was~~ approved prior to the date that Sections 1070, 1070.1 and 1070.2 became effective, must complete and submit this form and submit to the Board at its offices no later than 90 days from the effective date of these new requirements. Any student graduating from such a program or course will not be accepted to sit for examination or qualify for registration until this ~~form~~ Notice has been submitted to the Board. Certificates of Completion issued by educational course providers not meeting Notice submission requirements will not be recognized by the Board.

Rationale: Modified text Sections 1070, 1070.1 and 1070.2 all pertain to program and course providers and as such should be referenced in the above statement. Each Section includes both programs and course providers and should be reflected in the language as to all whom this Notice applies. Not all educational courses require State-administered examinations upon course completion and as such the Certificate of Course Completion

issued by the course provider should be referenced as being invalid in the event the course provider does not meet the Notice requirements.

3. Amend certifying statements on the Notice:

As noticed:

(1) I have read the attached regulations pertaining to ~~the approval of Registered Dental Assistant (RDA)~~ all dental assisting educational programs and courses, including Sections 1070, 1070.1 and 1070.2 of Title 16 of the California Code of Regulations;

(2) I have the authority to sign this Notice on behalf of the educational institution ~~or~~, program or course provider; and,

(3) That to the best of my knowledge, information and belief, the institution, organization or private course provider and its programs or courses for which I am responsible or duly authorized to represent complies with these regulations and can demonstrate to the Board having been in compliance with these regulations since _____ (insert date).

Rationale: As previously cited, Section 1070.1 is also applicable to the Notice requirements. Not all programs or courses are offered by institutional providers and as such approved organizations and private providers should be referenced in the Notice. Given that the educational regulations provide for the Board to exercise its right to site visit a program or course provider, we believe the certifying statement should address the program or courses ability to show proof of compliance at the request of the Board at any time, and that the certifying party should be made aware of such responsibility prior to signature.

4. Amend Notice to include verification of faculty or instructional staff and current Program Director:

CADAT is concerned about the lack of accurate staff information reported to the Board for all educational programs and courses. By including a verification table for the responsible party to submit demonstrating the current faculty, instructors and Directors, the Board will have the data necessary to ensure that those teaching courses are meeting the educational requirements and licensure/permit status to teach specific subject areas.

We thank you for your consideration of these Notice amendments and look forward to the opportunity to address this matter before the Board in the coming months.

Sincerely,

Lori Gagliardi, CDA, RDA, RDH, Ed.D.
Director – Policy Council

LaDonna Drury-Klein, CDA, RDA, BS
President

Tamara McNealy, RDA
Chair - Policy Council

Joy Myers, CDA, RDA, BS
Asst. Vice President/Policy Council

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
DENTAL BOARD OF CALIFORNIA
2005 Evergreen Street, Suite 1550, Sacramento, CA 95815
P 916-263-2300 F 916-263-2140 www.dbc.ca.gov

MEMORANDUM

DATE	October 26, 2010
TO	Dental Board Members Dental Board of California
FROM	Sarah Wallace Legislative & Regulatory Analyst
SUBJECT	**Agenda Item 5 (B):** Discussion and Possible Action to Consider Adoption of Amendments to Title 16, CCR, Sections 1070, 1070.1, 1070.2, 1071, and Proposed Additions to Title 16, CCR, Section 1070.6, 1070.7, 1070.8 for Dental Assisting Educational Programs and Courses

Background

Following the Board's consideration of comments received during the required 15-day modified text public, the Board may hold discussion and take action to adopt proposed amendments to Title 16, CCR, Sections 1070, 1070.1, 1070.2, 1071, and proposed additions to Title 16, CCR, Section 1070.6, 1070.7, 1070.8 for Dental Assisting Educational Programs and Courses.

Board Action Requested

Depending on the Board's action, staff requests one of the following:

A. If the Board adopts the final text as noticed and no changes are made, the Board must direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law and authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed amendments to Title 16, CCR, Sections 1070, 1070.1, 1070.2, 1071, and proposed additions to Title 16, CCR, Section 1070.6, 1070.7, 1070.8.

B. If the Board makes changes at the meeting to the text in response to any comments received, the Board must direct staff to take all steps necessary to complete the rulemaking process, including preparing a second modified text for an additional 15-day comment period, which includes the amendments accepted by the board at this meeting. 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 before completing the rulemaking process, and adopt amendments to Title 16, CCR, Sections 1070, 1070.1, 1070.2, 1071, and proposed additions to Title 16, CCR, Section 1070.6, 1070.7, 1070.8.

TITLE 16. DENTAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

SECOND MODIFIED TEXT

Changes to the originally proposed language are shown by double underline for new text and double strikeout for deleted text.

Changes to the first modified text are shown by bold italics with single underline for new text and bold italics with single strikeout for deleted text.

Amend Sections 1070, 1070.1, 1070.2, and 1071 and Adopt Sections 1070.6, 1070.7, 1070.8 of Division 10 of Title 16 of the California Code of Regulations, to read as follows:

Article 2. Educational Programs

~~**Section 1070. Approval of Registered Dental Assistant Educational Programs.**~~
~~(a) It is the intent of the board to approve only those educational programs for registered dental assisting which continuously maintain a high quality standard of instruction. Initial or continued approval shall be contingent upon compliance with these regulations.~~
~~(b) An educational program for registered dental assistants is one which has as its primary purpose providing post-secondary education in registered dental assisting and which encompasses educational training in the settings, foundation and application of all duties, functions and responsibilities assignable under these regulations to registered dental assistants. All approved programs shall include approved courses in coronal polishing and radiation safety pursuant to Sections 1014, 1014.1, and 1086(d)(15), but are not required to offer a course in the removal of excess cement from coronal surfaces of teeth under orthodontic treatment by means of an ultrasonic scaler.~~
~~(c) Each program shall apply for approval prior to operation. The board may approve, provisionally approve, or deny approval of any such program.~~
~~The board may, in lieu of conducting its own investigation, accept the findings of any commission or accreditation agency approved by the board and adopt those findings as its own. If a negative evaluation is made, the specific reasons therefore shall be provided to the program by the board in writing within 90 days after such negative evaluation was made.~~
~~(d) The processing times for RDA educational program approval are set forth in Section 1069. Each approved program shall be re-evaluated approximately every five years, but is subject to re-evaluation at any time if the board has reason to believe that the program may have violated these regulations.~~
~~(e) Program records shall be subject to inspection by the board at any time.~~

~~Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1753, Business and Professions Code.~~

1070. General Provisions Governing All Dental Assistant Educational Programs and Courses.

(a) (1) The criteria in subdivisions (b) to (h), inclusive, shall be met by a dental assisting program or course and all orthodontic assisting and dental sedation assisting permit programs or courses to secure and maintain approval by the board as provided in this article.

(2) The board may approve, provisionally approve, or deny approval of any program or course for which an application to the Board for approval is required. All RDA and RDAEF programs and dental assisting educational courses shall be re-evaluated approximately every seven years, but may be subject to re-evaluation and inspection by the Board at any time to review and investigate compliance with this article and the Act. Re-evaluation may include a site visit or written documentation that ensures compliance with all regulations. Results of re-evaluation shall be reported to the Board or its designee for final consideration and continuance of program or course approval, provisional approval and denial of approval.

(3) Program and course records shall be subject to inspection by the board at any time.

(4) The board may withdraw approval at any time that it determines that a program or course does not meet the requirements of this article or any other requirement in the Act. ~~established in this section or any other requirements of law.~~

(5) All programs and courses shall be established at the postsecondary educational level or deemed equivalent thereto by the board.

(6) The Board or its designee may approve, provisionally approve, or deny approval to any such program. Provisional approval shall not be granted for a period which exceeds beyond the length of the program. When the Board provisionally approves a program, it shall state the reasons therefore. Provisional approval shall be limited to those programs which substantially comply with all existing standards for full approval. A program given provisional approval shall immediately notify each student of such status. If the Board denies approval of a program, the specific reasons therefore shall be provided to the program by the Board in writing within 90 days after such action.

(b) The program or course director shall possess a valid, active, and current license issued by the board or the dental hygiene committee. The program or course director shall actively participate in and be responsible for the ~~day-to-day~~ administration of the program or course. Specifically, the program or course director shall be responsible for the following requirements:

(1) Maintaining for a period of not less than five years copies of curricula, program outlines, objectives, and grading criteria, and copies of faculty credentials, licenses, and certifications, and individual student records, including those necessary to establish satisfactory completion of the program or course.

(2) Informing the board of any major change to the program or course content, physical facilities, or faculty, within 10 days of the change.

(3) Ensuring that all staff and faculty involved in clinical instruction meet the requirements set forth in this article.

(c) Course faculty and instructional staff shall be authorized to provide instruction by the program or course director and the educational facility in which instruction is provided.

(~~c~~d) No faculty or instructional staff member shall instruct in any procedure that he or she does not hold a license or permit in California to perform. Each faculty or instructional staff member shall possess a valid, active, and current license issued by the Board or the Dental Hygiene Committee of California, shall have been licensed or permitted for a minimum of two years and possess experience in the subject matter he or she is teaching. An ~~faculty member~~ instructor who has held a license as a registered dental assistant or registered dental assistant in extended functions for at least two years, ~~and who holds a permit~~ who then becomes a permit holder as an Orthodontic Assistant on or after January 1, 2010 shall not be required to have held such a ~~certificate or~~ permit for two years in order to instruct in ~~such courses~~ the subject area.

(~~d~~e) A certificate, diploma, or other evidence of completion shall be issued to each student who successfully completes the program or course and shall include the following: the student's name, the name of the program or course, ~~the total number of program or course hours,~~ the date of completion, and the signature of the program or course director or his or her designee.

(~~e~~f) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties for which the program or course is approved to instruct.

(1) The location and number of general use equipment and armamentaria shall ensure that each student has the access necessary to develop minimum competency in all of the duties for which the program or course is approved to instruct. The program or course provider may either provide the specified equipment and supplies or require that the student provide them. Nothing in this section shall preclude a dental office that contains the equipment required by this section from serving as a location for laboratory instruction.

~~(2) The minimum requirement for armamentaria includes infection control materials specified by the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and~~

~~the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 , protective eyewear, mask, and gloves for each student and faculty member, and appropriate eye protection for each piece of equipment.~~

(~~3~~2) Clinical instruction shall be of sufficient duration to allow the procedures to be performed to clinical proficiency. Operatories shall be sufficient in number to allow a ratio of at least one operatory for every five students who are simultaneously engaged in clinical instruction.

(A) Each operatory shall contain functional equipment, including a power-operated chair for patient or simulation-based instruction in a supine position, operator and assistant stools, air-water syringe, adjustable light, oral evacuation equipment, work surface, handpiece connection, and adjacent hand-washing sink. ~~Minimum requirements are a power-operated chair for light, oral evacuation equipment, work surface, and adjacent hand-washing sink.~~

(B) Each operatory shall be of sufficient size to simultaneously accommodate one student, one instructor, and one patient or student partner.

(C) Prior to clinical assignments, students must demonstrate minimum competence in laboratory or preclinical performance of the procedures they will be expected to perform in their clinical experiences.

(~~f~~g) The program or course shall establish written clinical and laboratory protocols ~~to ensure adequate asepsis, infection, and hazard control and disposal of hazardous wastes,~~ that comply with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. The program or course shall provide these protocols to all students, faculty, and ~~appropriate~~ instructional staff to ensure compliance ~~with these protocols~~. Adequate space shall be provided for ~~preparing~~ handling, processing and sterilizing all armamentarium. ~~All reusable armamentarium shall be sterilized and nonreusable items properly disposed.~~

(~~g~~h) A written policy on managing emergency situations shall be made available to all students, faculty, and instructional staff. All faculty and staff involved in the direct ~~provision~~ oversight of patient care activities shall be certified in basic life support procedures, including cardiopulmonary resuscitation. Recertification intervals may not exceed two years. The program or course director shall ensure and document compliance by faculty and instructional staff. A program or course shall ~~not be required~~ sequence curriculum in such a manner so as to ensure that students complete instruction in basic life support prior to performing procedures on patients used for clinical instruction and evaluation.

(~~h~~i) A detailed program or course outline shall clearly state, in writing, the curriculum subject matter, ~~and specific instruction~~ hours of ~~in the individual areas of~~ didactic, laboratory, and clinical instruction~~.~~, ~~G~~general program or course objectives, ~~and specific~~ instructional ~~unit~~ objectives, ~~shall be stated in writing, and shall include, at a minimum,~~ theoretical ~~aspects~~ content of each subject, ~~as well as~~ and, where applicable, the use of practical application. Objective evaluation criteria shall be used for measuring student progress toward attainment of specific program or course objectives. Students shall be provided with all of the following:

(1) Specific ~~unit~~ performance objectives and the evaluation criteria ~~that will be used for all aspects of the curriculum including written, practical, and clinical~~ used for measuring levels of competence for each component of a given procedure including those used for examinations.

(2) Standards of performance that state the minimum number of satisfactory performances that are required for each performance-evaluated procedure.

(3) Standards of performance for laboratory, preclinical, and clinical functions, those steps that ~~constitute a critical error and~~ would cause the student to fail the ~~procedure~~ task being evaluated, ~~and~~ a description of each of the grades that may be ~~assessed for each procedure~~ utilized during evaluation procedures, and a defined standard of performance.

(~~i~~j) (1) As used in this article "extramural dental facility" means any clinical facility employed by a***n board-***approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary ***~~campus~~ location*** of the ***board-***approved program and in which dental treatment is rendered.

(2) If an extramural ~~clinical~~ dental facility is utilized, students shall, as part of an extramural organized program of instruction, be provided with planned, supervised clinical instruction. Laboratory and preclinical instruction shall be performed under the direct supervision of program or course faculty or instructional staff and shall not be provided in an extramural dental facility ~~facilities~~.

(~~2~~3) The program or course director, or a designated faculty member, shall be responsible for selecting extramural clinical sites and evaluating student competence ~~in performing procedures both~~ before and after the clinical assignment.

(~~3~~4) Prior to student assignment in an extramural dental facility, t~~T~~he program or course director, or a designated faculty or instructional staff member, shall orient dentists and all licensed dental healthcare workers who may provide instruction, evaluation and oversight of the student in the clinical setting. ~~who intend to provide extramural clinical facilities prior to the student assignment.~~ Orientation

shall include, at a minimum, the objectives of the program or course, the student's preparation for the clinical assignment, and a review of procedures and criteria to be used by the dentist or the licensed personnel in the extramural dental facility in evaluating the student during the assignment, which shall be the same as the evaluation criteria used within the program or course.
~~(4) The program or course faculty and extramural clinic personnel shall use the same objective evaluation criteria for grading.~~

(5) There shall be a written contract of affiliation between the program and each extramural dental ~~clinical~~ facility that includes written affirmation of compliance with the regulations of this Article. ~~Such contract shall contain the following:~~

~~(A) A description of settings in which the clinical training will be received,~~

~~(B) An affirmation that the dentist and clinic personnel acknowledge the legal scope of duties and infection control requirements,~~

~~(C) An affirmation that the clinical facility has the necessary equipment and armamentaria appropriate for the procedures to be performed,~~

~~(D) And an affirmation that the equipment and armamentaria are in safe operating condition.~~

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1750, 1750.2, 1750.4, 1752.1, 1752.4, 1752.6, and 1753, Business and Professions Code.

~~**Section 1070.1. Definitions.**~~
~~As used in Section 1070.2:~~
~~(a) "Didactic instruction" means lectures, demonstrations, and other instruction without active participation by students.~~
~~(b) "Laboratory or Pre-clinical instruction" means instruction in which students receive supervised experience performing functions using study models, manikins, or other simulation methods.~~
~~(c) "Clinical Externship instruction" means instruction in which students receive supervised experience in performing functions in the clinical setting on patients.~~

~~Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1753, Business and Professions Code.~~

1070.1. Educational Program and Course Definitions and Instructor Ratios
As used in this article, the following definitions shall apply:

(a) "Didactic instruction" means lectures, demonstrations, and other instruction involving theory ~~without~~ that may or may not involve active participation by students. The faculty or instructional staff of an educational institution or approved provider ~~or its designee~~

may provide didactic instruction via electronic media, home study materials, or live lecture modality. ~~methodology if the provider has submitted that content for approval.~~

(b) "Laboratory instruction" means instruction in which students receive supervised experience performing procedures using study models, mannequins, or other simulation methods. There shall be at least one instructor for every 14 students who are simultaneously engaged in ~~laboratory~~ instruction.

(c) "Preclinical instruction" means instruction in which students receive supervised experience within the educational facilities ~~experience~~ performing procedures on simulation devices or patients which are limited to students, faculty, or instructional staff members. There shall be at least one instructor for every six students who are simultaneously engaged in ~~preclinical~~ instruction.

(d) "Simulated clinical instruction" means instruction in which students receive supervised experience performing procedures using simulated patient heads mounted in appropriate position and accommodating an articulated typodont in an enclosed intraoral environment, or mounted on a dental chair in a dental operatory. Clinical simulation spaces shall be sufficient to permit one simulation space for each 2 students at any one time.

(~~d~~e) "Clinical instruction" means instruction in which students receive supervised experience in performing procedures in a clinical setting on patients. Clinical ~~instruction shall only be performed~~ procedures shall only be allowed upon successful demonstration and evaluation of laboratory and preclinical skills. There shall be at least one instructor for every six students who are simultaneously engaged in clinical instruction.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1750, 1750.2, 1750.4, 1752.1, 1752.4, 1752.6, and 1753, Business and Professions Code.

~~Section 1070.2. Requirements for Registered Dental Assistant Educational Programs.~~

~~The following minimum criteria shall be met for a registered dental assistant educational program to secure and maintain approval by the Board. Additional requirements may be stipulated when deemed necessary by the Board:~~

~~(a) Educational Setting. The program shall be established at the post-secondary educational level, or deemed equivalent thereto by the Board.~~

~~(b) Advisory Committee. Programs shall have an advisory committee consisting of an equal number of registered dental assistants and dentists, including at least two registered dental assistants and two dentists, all currently licensed by the Board. The advisory committee shall meet at least once each academic year with the program director, faculty and appropriate institutional personnel to monitor the ongoing quality and performance of the program. Programs that admit students at different phases shall meet at least twice each year.~~

~~(c) Administration/Faculty. Adequate provision for the supervision and operation of the program shall be made. The program must be staffed by faculty who are well-qualified in curricular subject matter, dental assisting functions, and educational methodology.~~

~~(1) The program director and each faculty member shall possess a valid, active, current license issued by the Board, and shall have a background in and current knowledge of dental assisting and registered dental assisting duties. A registered dental assistant faculty member shall possess certification in coronal polishing and radiation safety, and shall have been licensed as a registered dental assistant for at least four years.~~

~~(2) Effective two years after the effective date of this regulation, each faculty member shall have received a certificate of completion of an COMDA approved course in teaching methodology of at least 60 hours at a post-secondary institution prior to student instruction.~~

~~(3) Student contact hour loads must allow the faculty sufficient time for class preparation, student evaluation and counseling, and development of subject content and appropriate evaluation criteria and methods.~~

~~(4) The program director must have the education, background, and occupational experience necessary to understand and fulfill the program goals. He or she shall have teaching responsibilities which are less than those of a full-time faculty member. He/she shall actively participate in and be responsible for the day-to-day administration of the program including the following:~~

~~(A) Providing daily guidance of didactic, laboratory and clinical assignments.~~

~~(B) Maintaining for a period of not less than 5 years:~~

~~(1) Copies of curricula, course outlines, objectives, and grading criteria.~~

~~(2) Copies of faculty credentials, licenses, and certifications.~~

~~(3) Individual student records, including those necessary to establish satisfactory completion of all phases of the program, including clinical externship.~~

~~(4) Copies of minutes of all advisory committee meetings.~~

~~(C) Informing the Board of any changes to the program content, physical facilities, and/or faculty, at least 30 days prior to such change.~~

~~(D) Participating in budget preparation and fiscal administration, curriculum development and coordination, determination of teaching assignments, supervision and evaluation of faculty, establishment of mission criteria and procedures, design and operation of program facilities, and selection of extra-mural facilities and coordination of instruction in such facilities.~~

~~(E) Holding periodic faculty meetings to provide for subject matter correlation and curriculum evaluation, and to coordinate activities of full-time, part-time, and volunteer faculty.~~

~~(5) The owner and/or school administrator shall be responsible for the compliance of the program director with these regulations.~~

~~(d) Financial Resources. Sufficient financial resources to support the program and comply with these regulations shall be available. If the program or school requires approval by the California Department of Education and/or the Bureau for Private Post-secondary and Vocational Education, such approval must be obtained prior to application for Board approval by a new program and must be maintained at all times by~~

~~approved programs. Failure to maintain such approval shall result in the automatic withdrawal of board approval of the program.~~

~~(e) The program shall notify the Board, within 30 days after enrollment, of the names, and expected date of graduation of all students enrolled, and shall notify the Board of the names of program graduates within 30 days of graduation.~~

~~(f) Length of Program. The program shall be of sufficient duration for the student to develop minimum competence in performing dental assistant and registered dental assistant duties, but shall in no event be less than 720 clock hours.~~

~~(g) Evidence of Completion. A certificate, diploma, or other evidence of completion shall be issued to each student who successfully completes the program. A student shall be deemed to have successfully completed the program if the student has met all program requirements and has obtained passing scores on final written and practical examinations on all dental assistant and registered dental assistant duties.~~

~~(h) Facilities and Resources. Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in performing dental assistant and registered dental assistant duties. Such facilities shall include safe, adequate and educationally conducive:~~

~~(1) Lecture classrooms. Classroom size and equipment shall accommodate the number of students enrolled. Classrooms shall include: chalkboard or whiteboard, projection equipment, sufficient electrical outlets, adequate lighting and ventilation, and chairs and writing space for each student.~~

~~(2) Operatories. Operatories shall be sufficient in number to allow a ratio of at least one operatory for every five students at any one time, and shall be of sufficient size to accommodate an operator, a student, an instructor, and a patient at one time.~~

~~(A) Each operatory shall replicate a modern dental office containing functional equipment including: a power-operated chair for treating patients in a supine position; operator and assistant stools; dental units designed for application of current principles of dental assistant and registered dental assistant utilization; air-water syringe; adjustable light; slow speed and high-speed handpieces; oral evacuation equipment; work surface; view box; hand-washing sink; and all other armamentarium required to instruct dental assistant and registered dental assistant duties.~~

~~(B) Each operatory shall contain one training manikin with simulated face and tongue, full dentition, and water retrieval system.~~

~~(C) Each operatory must be of sufficient size to accommodate an operator, a student, an instructor, and a patient.~~

~~(3) Laboratories. The location and number of general use equipment, such as lathes, model trimmers, and vibrators shall assure that each student has the access necessary to develop minimum competency in performing all dental assistant and registered dental assistant duties. Protective eyewear is required for each piece of equipment.~~

~~During laboratory procedures, dental rotary equipment are required in the ratio of at least one for every three students, model trimmers in the ratio of at least one for every seven students, and vibrators in the ratio of at least one for every three students.~~

(4) Library. Provision shall be made for reasonable access to current and diverse dental/medical reference texts, current journals, audiovisual materials and other necessary resources. Library holdings shall include: nutrition, oral health education, preventive dentistry, dental materials, anesthesia and pain control, oral anatomy, oral histology, oral physiology, oral pathology, morphology, pharmacology, microbiology, chairside assisting, legal/ethical aspects of dentistry, radiology and radiation safety, sterilization/infection control, laboratory procedures, office emergency procedures, general dentistry, and specialty dentistry including, but not limited to, endodontics, oral and maxillofacial surgery, orthodontics, pediatric dentistry, periodontics, and prosthodontics.

(5) Armamentarium

(A) The number and variety of hand instruments shall be sufficient to instruct students in identifying and exchanging instruments, preparing procedural trays, and assisting in the diagnostic, operative and specialty procedures which are a part of general dentistry.

(B) Each student shall possess a pair of safety goggles for their exclusive use.

(C) One permanently preassembled tray for each procedure shall be provided for reference purposes. In addition, at least one set of hand instruments per chairside procedure for every two students shall be available during instruction of clinical, pre-clinical, and laboratory procedures.

(D) There shall be at least one functional typodont and bench mount for every two students, or comparable equipment if approved in advance by the Board. Each typodont shall have full dentition and soft gingivae.

(6) Infection Control. The program shall establish written pre-clinical, clinical, and laboratory protocols to ensure adequate asepsis, infection and hazard control, and disposal of hazardous wastes, which shall comply with the board's regulations and other Federal, State, and local requirements. The program shall provide such protocols to all students, faculty, and appropriate staff to assure compliance with such protocols. Adequate space shall be provided for preparing and sterilizing all armamentarium. All reusable armamentarium shall be sterilized, and a non-reusable items disposed of properly.

(7) Emergency Materials/Basic Life Support.

(A) A written policy on managing emergency situations must be made available to all students, faculty, and staff. Emergency materials shall include, but not be limited to, an oxygen tank which is readily available and functional. Medical materials for treating patients with life-threatening conditions must be available for instruction and accessible to the operatories. Facilities which do not treat patients must maintain a working model of a kit of such emergency materials for instructional purposes.

(B) All students, faculty, and staff involved in the direct provision of patient care must be certified in basic life support procedures, including cardiopulmonary resuscitation. Recertification intervals may not exceed two years. The program must document, monitor, and ensure compliance by such students, faculty, and staff, and keep a record of those who are not required to maintain such certification because they are medically or physically unable to perform such procedures.

~~(i) Program Content. The organization of the curriculum shall be balanced and flexible, creating opportunities for adjustments to changes in the practice of dentistry and registered dental assisting.~~

~~(1) Sufficient time shall be available for all students to obtain laboratory experience to achieve minimum competence in all dental assistant and registered dental assistant duties prior to the performance of procedures on patients.~~

~~(2) A detailed course outline shall be provided which clearly states curriculum subject matter and specific instruction hours for each topic in the individual areas of didactic, laboratory, pre-clinical, clinical, and externship instruction.~~

~~(3) There shall be no more than 14 students per instructor during laboratory instruction. There shall be no more than 6 students per instructor during pre-clinical and clinical instruction.~~

~~(4) Programs that admit students at different phases provide students with an orientation which shall include anatomy, tooth numbering, and universal precautions, including instrument sterilization, and which shall be successfully completed prior to participation in any other phase of the program.~~

~~(5) General program objectives and specific instructional unit objectives shall be stated in writing, and shall include theoretical aspects of each subject as well as practical application. The theoretical aspects of the program shall provide the content necessary for students to make judgments regarding the procedures which dental assistants and registered dental assistants are allowed to perform and to anticipate a dentist's needs during procedures performed in the practice of dentistry. The program shall assure that students who successfully complete the program can perform all dental assistant and registered dental assistant duties with minimum competence.~~

~~(6) Objective evaluation criteria shall be used for measuring student progress toward attainments of specific course objectives. Students shall be provided with specific unit objectives and the evaluation criteria that will be used for all aspects of the curriculum including written and practical examinations. The program shall establish a standard of performance which states the minimum number of satisfactory performances which are required for each procedure.~~

~~(7) Areas of didactic and laboratory demonstration instruction shall include at least the following:~~

~~(A) Biomedical - Dental Medical Emergencies, Basic Life Support, Nutrition and Preventive Dentistry;~~

~~(B) Dental Science - Dental Materials, Oral Anatomy and Physiology, Oral Pathology, Pharmacology, Morphology and Microbiology;~~

~~(C) Dental Assisting - General and Specialty Dentistry, Chairside Assisting, Legal/Ethical Aspects of Dentistry; Patient Management; Infection Control;~~

~~(D) All functions dental assistants and registered dental assistants are allowed to perform by statute or regulation.~~

~~(j) Externship Instruction. Students shall, as part of an organized program of instruction, be provided with planned, supervised clinical instruction in performing all dental assistant and registered dental assistant duties.~~

~~(1) The program director/coordinator or a dental faculty member shall be responsible for selecting extern clinical sites and evaluating student competence in performing procedures both before and after the clinical assignment.~~

~~(2) Objective evaluation criteria shall be used by the program faculty and clinic personnel.~~
~~(3) Program faculty shall visit each extramural clinical facility at least once every ten clinical days.~~
~~(4) Dentists who intend to provide extramural clinical practices shall be oriented by the program director/coordinator or a dental faculty member prior to the student assignment. Orientation shall include the objectives of the program, the preparation the student has had for the clinical assignment, and a review of procedures and criteria to be used by the dentist in evaluating the student during the assignment.~~
~~(5) There shall be a written contract of affiliation with each extramural clinical facility utilized by the program. Such contact shall describe the settings in which the clinical training will be received, affirm that the clinical facility has the necessary equipment and armamentarium appropriate for the procedures to be performed, and affirm that such equipment and armamentarium are in safe operating condition.~~
~~(6) The program shall maintain documentation that students completed clinical training in all dental assisting and registered dental assisting functions during the clinical externship phase of the program.~~

~~Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1753, Business and Professions Code.~~

1070.2. Approval of Registered Dental Assistant Educational Programs
(a) ~~A registered dental assistant program~~ All Registered Dental Assistant programs in California shall apply for and receive board approval prior to operation.

(b) The Board may, in lieu of conducting its own investigation, accept the findings of any commission or accreditation agency approved by the Board and adopt those findings as its own. All programs accredited by the American Dental Association Commission on Dental Accreditation (Commission) shall submit to the Board after each site visit a copy of the final report of the Commission's findings within 30 days of the final report issuance. New programs approved by the Commission shall apply to the Board and shall submit proof of Provisional Approval status by the Commission, a copy of the institutional self study and applications for Radiation Safety, Coronal Polish, Pit and Fissure Sealants and any other courses required of an RDA educational program. Acceptance of the Commission's or any accrediting agencies' findings is at the discretion of the Board and does not prohibit the Board from exercising its right to site evaluate a program.

(c) If the program is granted the status of "Approved with Reporting Requirements" from the Commission, the program shall submit to the Board copies of any and all correspondence received from or submitted to the Commission until such time as the status of "Approval without Reporting Requirements" is granted. Additionally, if the program withdraws from accredited status by the Commission, the program shall notify the Board, in writing, of such status within 30 days.

(~~b~~d) In order for a registered dental assistant program to secure and maintain approval by the board, it shall meet the requirements of sections 1070 and 1070.1 and the requirements contained in this section.

(1) A program shall notify the board in writing if it wishes to increase the maximum student enrollment for which it is approved and shall provide ~~sufficient additional~~ documentation to the board to demonstrate compliance with Section 1070 and Section 1070.1 to reapprove the program for the increased enrollment prior to accepting additional students.

(2) Programs shall ~~have~~ establish and maintain an advisory committee ~~consisting of an equal number of registered dental assistants and dentists, including at least two registered dental assistants and two dentists~~ whose membership provides for equal representation of dentists and dental assistants, all currently licensed by the board. In addition, consideration shall be given to a student, a recent graduate or a public representative to serve on the advisory committee. The advisory committee shall meet at least once each academic year with the program director, faculty, and appropriate institutional personnel to monitor the ongoing quality and performance of the program and to receive advice and assistance from the committee. ~~Programs that admit students at different phases shall meet at least twice each year.~~

(3) Adequate provision for the supervision and operation of the program shall be made. In addition to the requirements of sections 1070 and 1070.1, the following requirements shall be met:

~~(A) Each program faculty member shall have successfully completed a board-approved course in the application of pit and fissure sealants.~~

(~~B~~A) By January 1, 2012, each faculty member shall have completed a ~~board-approved~~ course or certification program in ~~instructional~~ educational methodology of at least 30 hours, unless he or she holds any one of the following: a postgraduate degree in education, a Ryan Designated Subjects Vocational Education Teaching Credential, a Standard Designated Subjects Teaching Credential, or, a Community College Teaching Credential. Each faculty member employed ~~on or~~ after January 1, 2012, shall complete a course or certification program in ~~instructional~~ educational methodology within six months of employment. The program director or designated administrator shall be responsible to obtain and maintain records of each faculty member showing evidence of having met this regulation.

(~~C~~B) The program director shall have teaching responsibilities that are less than those of a full-time faculty member. He or she shall actively participate in and be responsible for the ~~day-to-day~~ administration of the program including the following:

(i) Participating in budget preparation and fiscal administration, curriculum development and coordination, determination of teaching assignments, supervision and evaluation of faculty, establishment of ~~mission~~ criteria and procedures, design and operation of program facilities, and selection of extramural facilities and coordination of instruction in those facilities.
(ii) Holding periodic ~~faculty~~ staff meetings to provide for subject matter ~~correlation and~~ review, instructional calibration, curriculum evaluation, and coordinating activities of full-time, part-time, and volunteer faculty or instructional staff.

(iii) Maintaining for not less than five years' copies of minutes of all advisory committee and staff meetings.

(~~D~~C) The owner or school administrator shall be responsible for the compliance of the program director with the provisions of this section and Sections 1070 and 1070.1.

(4) The program shall have sufficient financial resources available to support the program and to comply with this section. If the program or school requires approval by any other governmental agency, that approval shall be obtained prior to application to the board for approval and shall be maintained at all times. The failure to maintain that approval shall result in the automatic withdrawal of board approval of the program.

(5) The program shall be of sufficient duration for the student to develop minimum competence in performing dental assistant and registered dental assistant duties, but in no event less than 800 hours, including at least 275 hours of didactic instruction, at least 260 hours of combined laboratory or preclinical instruction conducted in the program's facilities under the direct supervision of program faculty or instructional staff, and~~, at least 85 hours of preclinical and clinical instruction conducted in the program's facilities under the direct supervision of program faculty, and~~ the remaining hours utilized in clinical instruction in extramural ~~clinical~~ dental facilities. No more than 20 hours of instruction shall be devoted to ~~instruction in~~ clerical, administrative, practice management, or similar duties. Programs whose demonstrated total hours exceed 800 and who meet all the instructional requirements in this section, may utilize the additional instructional hours as deemed appropriate for program success. 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 Registered Dental Assistant Educational Programs (New 9/10)" within ninety (90) days of the effective date of these regulations.

(6) In addition to the requirements of Section 1070 with regard to extramural instruction:

(A) No more than 25 percent of extramural clinical instruction shall take place in a specialty dental practice.

(B) Program faculty shall visit each extramural clinical facility at least once every ten clinical days.

(7) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties that registered dental assistants are authorized to perform. The following requirements are in addition to those contained in Sections 1070 and 1070.1:

(A) The following are minimum requirements for equipment and armamentaria during laboratory, preclinical, and clinical sessions as appropriate to each type of session: amalgamator, model trimmers in the ratio of one for every seven students, dental rotary equipment in the ratio of one for every three students, vibrators in the ratio of one for every three students, light curing devices in the ratio of one for every operatory, functional typodonts and bench mounts in the ratio of one for every two students, functional orthodontically banded typodonts in the ratio of one for every four students, facebows in the ratio of one for every ten students, automated blood pressure device, EKG machine, pulse oximeters in the ratio of one for every ten students, capnograph or simulated device, one ~~sets~~ of hand instruments in the ratio of one set for every two students for each procedure, respiration device, camera for intraoral use, camera for extraoral use, CAD machine or simulated device, caries detection device in the ratio of one for every ten students, and all other equipment and armamentaria required to teach dental assistant and registered dental assistant duties. With the exception of ***a CAD machine or*** patient monitoring equipment specific to EKG machine, ~~***and***~~ pulse oximeter, ***and capnograph*** the program shall own the necessary equipment and have it readily available upon inspection. Patient monitoring equipment owned by the institution and utilized by more than one program within the institution premises is acceptable and may be used by the RDA program as needed for instruction. Instruction by a licensed healthcare provider is acceptable. In the event instruction in patient monitoring procedures ***and use of the CAD machine*** is provided by an outside provider, the RDA program shall not be required to have available or own patient monitoring equipment ***or CAD machine***.

(B) ~~One permanently preassembled tray for each procedure shall be provided for reference purposes.~~ Instruments must be provided to accommodate students needs in learning to identify, exchange, prepare procedural trays and assist in procedures as they relate to general and specialty dentistry.

(C) Provision shall be made for reasonable access to current and diverse dental and medical reference texts, current journals, audiovisual materials, and other necessary resources. Library holdings, which may include, in total or in part, access through the Internet, shall include materials relating to all subject areas of the program curriculum.

(D) Emergency materials shall include, at a minimum, an oxygen tank that is readily available and functional. Medical materials for treating patients with life-threatening conditions shall be available for instruction and accessible to the operatories. Facilities that do not treat patients shall maintain a working model of a kit of such emergency materials for instructional purposes.

(8) ~~The curriculum shall be established, reviewed, and amended as necessary to allow for changes in the practice of dentistry and registered dental assisting.~~ Curriculum documentation shall be reviewed annually and revised, as needed, to reflect new concepts and techniques. This content must be integrated and of sufficient depth, scope, sequence of instruction, quality and emphasis to ensure achievement of the curriculum's defined competencies.

(A) Programs that admit students in phases, including modular or open-entry programs, shall provide, at minimum, ~~students with~~ basic instruction ~~prior to participation in any other portion of the program that shall, at a minimum, include~~ in tooth anatomy, tooth numbering, general program guidelines, basic chairside skills, emergency and safety precautions, ~~and~~ infection control and sterilization protocols associated with and required for patient treatment. Such instruction shall occur prior to any other program content and prior to performances or activities involving patients.

(B) All programs shall provide students with additional instruction in the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 prior to the student's performance of procedures on patients.

(9) In addition to the requirements of Sections 1070 and 1070.1 and subdivisions (b) (11) and (b) (12) of this section, programs shall include the following content:

(A) ~~A radiation safety course~~ Instruction in radiation safety that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 1, Article 3.1, Sections 1014 and 1014.1.

(B) ~~A coronal polishing course~~ Instruction in coronal polishing that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.4.

(C) ~~A pit and fissure sealant course~~ Instruction in the application of Pit and Fissure Sealants that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.3.

(D) A course in basic life support provided by an instructor approved by the American Red Cross or the American Heart Association, or any other course approved by the board as equivalent. The program may require that the student complete this course as a prerequisite to program enrollment, or that the student provide evidence of having completed the course from another provider.

(E) ~~An Infection control course~~Instruction in infection control that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.6.

(F) Instruction in the Dental Practice Act that includes the content specified in the California Code of Regulations, Title 16, Division 10, Chapter 1, Article 4, Section 1016 governing Dental Practice Act continuing education courses.

(10) A program that desires to provide instruction in the following areas shall apply separately for approval to provide the following courses:

(A) A course in the removal of excess cement with an ultrasonic scaler, which course shall meet the requirements of California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.5.

(B) An orthodontic assistant permit course that shall meet the requirements of California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.7, except that a program shall not be required to obtain separate approval to teach the duties of placing ligature ties and archwires, removing orthodontic bands, and removing excess cement from surfaces of teeth with a hand instrument, and shall be no less than 60 hours, including at least 12 hours of didactic instruction, at least 26 hours of laboratory instruction, and at least 22 hours of clinical instruction.

(C) A dental sedation assistant permit course that shall meet the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.8.

(D) A Registered Dental Assisting educational program that includes instructional content for either the orthodontic assistant permit or dental sedation assistant permit or both, shall provide a certificate or certificates of completion to the graduate. The certificate holder shall be deemed an

eligible candidate for the permit examination process as having met all educational requirements for the permit examination.

(11) General didactic instruction shall include, at a minimum, the following:

(A) Principles of general anatomy, physiology, oral embryology, tooth histology, and head-neck anatomy.

(B) Principles of ~~abnormal~~ conditions related to and including oral pathology, orthodontics, periodontics, endodontics, pediatric dentistry, oral surgery, prosthodontics, and esthetic dentistry.

(C) ~~Legal requirements and ethics related to scope of practice, unprofessional conduct, and, patient records and confidentiality.~~ Instruction in the Dental Practice Act that includes the content specified in the California Code of Regulations, Title 16, Division 10, Chapter 1, Article 4, Section 1016, as well as principles of HIPAA privacy and security standards, risk management and professional codes of ethical behavior.

(D) Principles of infection control, waste management and hazardous communication requirements in compliance with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. Instruction in infection control shall meet the education requirements set forth in Section 1070.6(e).

(E) Principles ~~and federal, state, and local requirements~~ related to pharmacology and biomedical sciences including nutrition and microbiology.

(F) Principles of medical-dental emergencies and first aid management~~, including symptoms and treatment~~.

(G) Principles of the treatment planning process including medical health history data collection, patient and staff confidentiality, and charting.

(H) Principles of record classifications including management, storage, and retention protocol for all dental records including the legal and ethical issues involving patient records.

(I) Principles and protocols of special needs patient management, the psychology and management of dental patients, and overall interpersonal relationships.

(J) Principles, protocols, and armamentaria associated with all dental assisting chairside procedures.

(K) Principles, protocols, manipulation, use, and armamentaria for contemporary dental materials used in general and specialty dentistry.

(L) Principles and protocols for oral hygiene preventative methods including, plaque identification, toothbrushing and flossing techniques, and nutrition.

(M) Principles, protocols, armamentaria, and procedures associated with operative and specialty dentistry.

(N) Principles, protocols, armamentaria, and procedures for each duty that dental assistants and registered dental assistants are allowed to perform.

(O) All content for instruction in radiation safety as set forth in California Code of Regulations, Title 16, Division 10, Chapter 1, Article 3.1, Section 1014.1.

(P) All content for instruction in coronal polishing as set forth in California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.4.

(Q) All content for instruction in the application of Pit and Fissure Sealants as set forth in California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.3.

(12) Laboratory and clinical instruction shall be of sufficient duration and content for each student to achieve minimum competence in the performance of each procedure that dental assistant and registered dental assistant is authorized to perform.

(13) 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.

~~(c) The board may at any time conduct a thorough evaluation of an approved educational program's curriculum and facilities to determine whether the program meets the requirements for continued approval.~~

~~(d) The board may, in lieu of conducting its own investigation, accept the findings of any commission or accreditation agency approved by the board and adopt those findings as its own.~~

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1752.1, 1752.4, and 1752.6, Business and Professions Code.

1070.6. Approval of Infection Control Courses

In addition to the requirements of Sections 1070 and 1070.1, the following criteria shall be met by a course in infection control, as required in Sections 1750, 1750.2, 1750.4, and 1752.1, to secure and maintain approval by the board:

(a) Adequate provisions for the supervision and operation of the course in infection control shall be made in compliance with Section 1070. Notwithstanding Section 1070, faculty shall not be required to be licensed by the board, but faculty shall have experience in the instruction of the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005. In addition ~~to the requirements of Section 1070~~, all faculty responsible for clinical evaluation shall have completed a two-hour methodology course in clinical evaluation.

(b) A course in infection control shall be of sufficient duration for the student to develop minimum competency in all aspects of the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005, but in no event less than eight hours, including at least four hours of didactic instruction, at least two hours of laboratory or preclinical instruction, and at least two hours of clinical instruction. Preclinical instruction shall utilize instruments, surfaces, and situations where contamination is simulated, without actual contamination, from bloodborne and other pathogens being present.

(c) The minimum requirements for equipment and armamentaria shall include personal protective equipment, FDA-approved sterilizer, ultrasonic unit or instrument processing device, sharps container, selection of instruments, equipment, and armamentaria that are necessary to instruct or demonstrate proper hazardous waste disposal, consistent with the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2, local, state, and federal mandates, and all other armamentaria required to instruct or properly demonstrate the subjects described in the course content.

(d) Areas of instruction shall include, at a minimum, the instruction specified in subdivisions (e) and (f).

(e) Didactic instruction shall include, at a minimum, the following as they relate to the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005:

(1) Basic dental science and microbiology as they relate to infection control in dentistry.

(2) Legal and ethical aspects of infection control procedures.

(3) Terms and protocols specified in the California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 regarding the minimum standards for infection control.

(4) Principles of modes of disease transmission and prevention.
(5) Principles, techniques, and protocols of hand hygiene, personal protective equipment, surface barriers and disinfection, sterilization, sanitation, and hazardous chemicals associated with infection control.

(6) Principles and protocols of sterilizer monitoring and the proper loading, unloading, storage, and transportation of instruments to work area.

(7) Principles and protocols associated with sharps management.

(8) Principles and protocols of infection control for laboratory areas.

(9) Principles and protocols of waterline maintenance.

(10) Principles and protocols of regulated and nonregulated waste management.

(11) Principles and protocols related to injury and illness prevention, hazard communication, general office safety, exposure control, postexposure requirements, and monitoring systems for radiation safety and sterilization systems.

(f) Preclinical instruction shall include three experiences in the following areas, with one used for a practical examination:

(1) Apply hand cleansing products and perform hand cleansing techniques and protocols.

(2) Apply, remove, and dispose of patient treatment gloves, utility gloves, overgloves, protective eyewear, masks, and clinical attire.

(3) Apply the appropriate techniques and protocols for the preparation, sterilization, and storage of instruments including, at a minimum, application of personal protective equipment, precleaning, ultrasonic cleaning, rinsing, sterilization wrapping, internal or external process indicators, labeling, sterilization, drying, storage, and delivery to work area.
(4) Preclean and disinfect contaminated operatory surfaces and devices, and properly use, place, and remove surface barriers.

(5) Maintain sterilizer including, at a minimum, proper instrument loading and unloading, operation cycle, spore testing, and handling and disposal of sterilization chemicals.

(6) Apply work practice controls as they relate to the following classification of sharps: anesthetic needles or syringes, orthodontic wires, and broken glass.

(7) Apply infection control protocol for the following laboratory devices: impressions, bite registrations, and prosthetic appliances.

(8) Perform waterline maintenance, including use of water tests and purging of waterlines.

(g) Clinical instruction shall include two experiences in the following areas, with one used for a clinical examination:

(1) Apply hand cleansing products and perform hand cleansing techniques and protocols.

(2) Apply, remove, and dispose of patient treatment gloves, utility gloves, overgloves, protective eyewear, masks, and clinical attire.

(3) Apply the appropriate techniques and protocols for the preparation, sterilization, and storage of instruments including, at a minimum, application of personal protective equipment, precleaning, ultrasonic cleaning, rinsing, sterilization wrapping, internal or external process indicators, labeling, sterilization, drying, storage, and delivery to work area.

(4) Preclean and disinfect contaminated operatory surfaces and devices, and properly use, place, and remove surface barriers.

(5) Maintain sterilizer including, at a minimum, proper instrument loading and unloading, operation cycle, spore testing, and handling and disposal of sterilization chemicals.

(6) Apply work practice controls as they relate to the following classification of sharps: anesthetic needles or syringes, orthodontic wires, and broken glass.

(7) Apply infection control protocol for the following laboratory devices: impressions, bite registrations, and prosthetic appliances.

(8) Perform waterline maintenance, including use of water tests and purging of waterlines.(h) 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.

(h) 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 Infection Control Courses (New 10/10)" within ninety (90) days of the effective date of these regulations.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1750, 1750.2, 1750.4, and 1752.1, Business and Professions Code.

1070.7. Approval of Orthodontic Assistant Permit Courses

In addition to the requirements of Sections 1070 and 1070.1, the following criteria shall be met by a orthodontic assistant permit course to secure and maintain approval by the board.

(a) The course shall be of sufficient duration for the student to develop minimum competence in all of the duties that orthodontic assistant permitholders are authorized to perform, but in no event less than 84 hours, including at least 24 hours of didactic instruction, at least 28 hours of laboratory instruction, and at least 32 hours of clinical instruction. A registered dental assistant shall not be required to complete further instruction in the duties of placing ligature ties and archwires, removing orthodontic bands, and removing excess cement from tooth surfaces with a hand instrument. The course hours for a student who holds a valid and current registered dental assistant license shall be no less than 55 hours, including 11 didactic hours, 24 laboratory hours, and 20 clinical hours. A registered dental assistant who has completed a board-approved course in the use of an ultrasonic scaler shall not be required to complete further instruction in that duty. The course hours for a student who holds a valid and current registered dental assistant license and who has completed a Board-approved course in the use of an ultrasonic scaler shall be no less than 51 hours, including 9 didactic, 22 laboratory, and 20 clinical.

(b) The minimum requirements for equipment and armamentaria shall include banded or bonded orthodontic typodonts in the ratio of at least one for every four students, bench mount or dental chair mounted mannequin head, curing light, regular typodont with full dentition and soft gingiva in the ratio of at least one for every four students, ~~and~~ a selection of orthodontic instruments and adjunct material for all of the procedures that orthodontic assistant permitholders are authorized to perform under Business and Professions Code Section 1750.3.

(c) In addition to the requirements of Section 1070, a~~A~~ll faculty or instructional staff members responsible for clinical evaluation shall have completed a two-hour methodology course in clinical evaluation prior to conducting clinical evaluations of students.

(d) Areas of instruction shall include, at a minimum, the instruction specified in subdivisions (e) to (j), inclusive, as well as, instruction in basic background information on orthodontic practice."Basic background information on orthodontic practice" means,

for purposes of this subdivision, the orthodontic treatment review, charting, patient education, and legal and infection control requirements as they apply to orthodontic practice.

(e) The following requirements shall be met for sizing, fitting, cementing, and removing orthodontic bands:

(1) Didactic instruction shall contain the following:

(A) Theory of band positioning and tooth movement.

(B) Characteristics of band material: malleability, stiffness, ductility, and work hardening.

(C) Techniques for orthodontic banding and removal, which shall include all of the following:

(i) Armamentaria.

(ii) General principles of fitting and removing bands.

(iii) Normal placement requirements of brackets, tubes, lingual sheaths, lingual cleats, and buttons onto bands.

(iv) Orthodontic cements and adhesive materials: classifications, armamentaria, and mixing technique.

(v) Cementing bands: armamentaria, mixing technique, and band cementation procedures.

(vi) Procedure for removal of bands after cementation.

(2) Laboratory instruction shall include typodont experience in the sizing, fitting, cementing, and removal of four posterior first molar bands a minimum of two times, with the cementing and removal of two first molar bands used as a practical examination.

(3) Clinical instruction shall include the sizing, fitting, cementing, and removal of four posterior first molar bands on at least two patients.

(f) The following requirements shall be met for preparing teeth for bonding:

(1) Didactic instruction shall contain the following:

(A) Chemistry of etching materials and tooth surface preparation

(B) Application and time factors

(C) Armamentaria

(D) Techniques for tooth etching.

(2) Laboratory instruction shall include typodont experience with etchant application in preparation for subsequent bracket bonding on four anterior and four posterior teeth a minimum of four times each, with one of each of the four times used for a practical examination.

(3) Clinical instruction shall include etchant application in preparation for bracket bonding on anterior and posterior teeth on at least two patients.

(g) The following requirements shall be met for bracket positioning, bond curing, and removal of orthodontic brackets.

(1) Didactic instruction shall include the following elements:

(A) Characteristics and methods of orthodontic bonding.

(B) Armamentaria.

(C) Types of bracket bonding surfaces.

(D) Bonding material characteristics, application techniques, and curing time factors.

(E) Procedure for direct and indirect bracket bonding.

(F) Procedures for bracket or tube removal.

(2) Laboratory instruction shall contain typodont experience with selecting, prepositioning, tooth etching, positioning, curing and removing of four anterior and four posterior brackets a minimum of four times each, with one each of the four times used for a practical examination.

(3) Clinical instruction shall contain selecting, adjusting, prepositioning, etching, curing and removal of anterior and posterior brackets on at least two patients.

(h) The following requirements shall be met for archwire placement and ligation:

(1) Didactic instruction shall contain the following:

(A) Archwire characteristics.

(B) Armamentaria.

(C) Procedures for placement of archwire previously adjusted by the dentist.

(D) Ligature systems, purpose and types, including elastic, wire, and self-ligating.

(2) Laboratory instruction shall contain typodont experience on the following:

(A) The insertion of a preformed maxillary and mandibular archwire a minimum of four times per arch, with one of each of the four times used for a practical examination.

(B) Ligation of maxillary and mandibular archwire using elastic or metal ligatures or self-ligating brackets a minimum of four times per arch, with one of each of the four times used for a practical examination.

(3) Clinical instruction shall contain the following:

(A) Insertion of a preformed maxillary and mandibular archwire on at least two patients.

(B) Ligating both preformed maxillary and mandibular archwires using a combination of elastic and metal ligatures or self-ligating brackets on at least two patients for each.

(i) The following requirements shall be met for cement removal with a hand instrument:

(1) Didactic instruction shall contain the following:

(A) Armamentaria

(B) Techniques of cement removal using hand instruments and related materials

(2) Laboratory instruction shall contain typodont experience on the removal of excess cement supragingivally from an orthodontically banded typodont using a hand instrument four times, with one of the four times used for a practical examination.

(3) Clinical instruction shall contain removal of excess cement supragingivally from orthodontic bands with a hand instrument on at least two patients.

(j) Instruction for cement removal with an ultrasonic scaler shall be in accordance with the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section

1070.5 governing courses in the removal of excess cement from teeth under orthodontic treatment with an ultrasonic scaler.

(k) 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.

(l) 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 Orthodontic Assistant Permit Courses (New 10/10)" within ninety (90) days of the effective date of these regulations.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1750.2 and 1752.4, Business and Professions Code.

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 section, the following definitions apply: "IV" means "intravenous", "AED" means automated external defibrillator, "CO2" means carbon dioxide, and ""ECG" or "EKG" means electrocardiogram.

(a) (1) In addition to the requirements of Section 1070, all faculty or instructional staff members responsible for clinical evaluation shall have completed a two-hour methodology course in clinical evaluation prior to conducting clinical evaluations of students.The course director, designated faculty member, or instructional staff member ~~or faculty~~ may, in lieu of a license issued by the board, possess a valid, active, and current license issued in California as a ~~certified registered nurse anesthetist or~~ a physician and surgeon.

(2) ~~All faculty~~ 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 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 sedation or general anesthesia, who shall be at the patient's chairside while conscious 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 ~~***duties tasks***~~ described in ~~***Section 1750.5 of the Code subdivisions (j), (k), (l), (m), and (n) of this Section***~~ during no less than twenty (20) supervised cases utilizing conscious sedation or general anesthesia.

(c)~~(1)~~ The following are minimum requirements for equipment and armamentaria:

(1) O~~o~~ne 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 that the California Code of Regulations, Title 16, Division 10, Chapter 2, Article 5, Section 1043 require for the administration of general anesthesia or conscious 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.

(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.

(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 (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 sedation, deep sedation, and general anesthesia.

(7) Overview of patient monitoring during conscious sedation and general anesthesia.

(8) Prevention, recognition, and management of complications.

(9) Obtaining informed consent.

(f)~~(1)~~ With respect to medical emergencies, didactic instruction shall contain:

(1) A~~a~~n 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 section.

~~Instruction shall include at least two experiences each, one of each of which shall be used for a practical examination.~~

(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 sedation, deep sedation, and general anesthesia.

(4) Review of respiratory and circulatory physiology and related anatomy, with special emphasis on establishing and maintaining a patent 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.

(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 but not be limited to, 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 or conscious 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 ECG/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 ECG/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 section. ~~shall include at least three experiences on another student or staff person for each of the following, one of each of which shall be used for an examination. Clinical instruction shall include at lease three experiences on a patient human subjects for each of the following, one of each of which shall be used for a clinical examination:~~

(A) Assessment of blood pressure and pulse both manually and utilizing an automatic system.

(B) Placement and assessment of an electrocardiogram (ECG/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: The student shall demonstrate proficiency in each of the following tasks, under supervision of faculty or instructional staff as described in section 1070.8(a)(3), utilizing patients and shall then be eligible to complete an examination on this section. ~~shall include at least three experiences on a patient for each of the following, one of each of which shall be used for a clinical examination:~~

(A) Assessment of blood pressure and pulse both manually and utilizing an automatic system.

(B) Placement and assessment of an electrocardiogram (ECG/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.~~

(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 ~~and clinical~~ 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 section. ~~shall include at least three experiences on a student or staff person for each of the following, one of each of which shall be used for an examination:~~

(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: 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), utilizing patients and shall then be eligible to complete an examination on this section. ~~shall include at least three experiences on a patient for each of the following, one of which shall be used for a clinical examination:~~

(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 ~~shall include at least three experiences 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~~, one of which shall be for~~ a practical examination.

(3) Clinical instruction: The student shall demonstrate proficiency in the ~~shall include at least three experiences 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 section.~~ the extramural facility dentist.~~

(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 ~~shall include at least three experiences of~~ 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 section.~~ one of which shall be used for a practical examination.~~

(3) Clinical instruction: The student shall demonstrate proficiency in ~~shall include at least three experiences~~ 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 section. ~~on at least three patients in the presence of a licensed dentist.~~

(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 ~~shall include at least three experiences~~ on a venipuncture training arm or in a simulated environment for IV removal, ands shall be eligible for a practical examination. ~~one of which shall be used for a practical examination.~~

(3) Clinical instruction: The student shall demonstrate proficiency in ~~shall include at least three experiences~~ removing IV lines ~~on at least three patients~~ 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 section. ~~a licensed dentist.~~

(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)" within ninety (90) days of the effective date of these regulations.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1750.4, Section 1750.5 and 1752.4, Business and Professions Code.

Section 1071. Approval of RDAEF Educational Programs.

~~(a) A single standard of care shall be maintained and the board shall approve only those educational programs for dental assisting in extended functions which continuously maintain a high quality standard of instruction. The requirements contained in this article are designed to that end and govern the approval of educational programs for RDAEF's. Continuation of approval will be contingent upon compliance with these requirements.~~
~~(b) An educational program for RDAEF's is one which has as its primary purpose providing post-secondary education in extended function dental assisting and which encompasses educational training in the settings, foundation and application of all duties, functions and responsibilities assignable under these regulations to registered dental assistants in extended functions.~~

(c) A new educational program for RDAEF's shall apply for approval prior to operation. The Board may approve, provisionally approve, or deny approval of any such program. Provisional approval shall not be granted for a period which exceeds the length of the program and in no event for more than 30 days. When the board provisionally approves a program, it shall state the reasons therefore. Provisional approval shall be limited to those programs which substantially comply with all existing standards for full approval. A program given provisional approval shall immediately notify each student of such status.
The Board may, in lieu of conducting its own investigation, accept the findings of any commission or accreditation agency approved by the Board and adopt those findings as its own. If the Board denies approval of a program, the specific reasons therefor shall be provided to the program by the Board in writing within 90 days after such action.
(d) The processing times for RDAEF educational program approval are set forth in Section 1069.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1614 and 1756, Business and Professions Code, and Section 15376, Government Code.

Section 1071.1. Requirements for Approval of RDAEF Educational Programs.
The following criteria must be met by a dental assisting educational program in extended functions to secure and maintain approval by the board:
(a) Licensure Requirements for Students - All students must possess valid, active certificates as registered dental assistants issued by the board in order to be admitted to the program.
(b) Education Setting - The program shall be established at the postsecondary educational level.
(c) Administration/Clinical Training. - The clinical training shall be given at a dental school or facility which has a written contract of affiliation for such training with a dental school. An extension program of a university shall not be considered a dental school. Such written contract of affiliation shall include a description of the settings in which the clinical training may be received and shall provide for direct supervision of such training by faculty designated by the dental school. An affiliated facility shall not include a private dental office unless such office is a site approved by the Board on recommendation of a dental school. Each RDAEF educational program shall provide clinical facilities and clinical resources necessary to accomplish training of duties assigned to the RDAEF.
(d) Facilities.
(1) There shall be a sufficient number of safe, modern lecture classroom operatories, X-ray operatories, and laboratories for use by the students.
(2) All students shall have access to modern equipment in order to develop extended functions dental assisting skills.
(3) Adequate sterilizing facilities shall be provided.
(e) Curriculum Organization/Learning Resources.
(1) The organization of the curriculum for RDAEF's shall be flexible, creating opportunities for adjustments to and research of, advances in the practice of registered dental assisting in extended functions.

~~(2) Students shall have reasonable access to dental/medical reference texts, current journals, audio visual materials and other relevant resources.~~
~~(3) Curriculum shall provide students with a basic understanding of extended function dental assisting procedures and an ability to perform procedures with competence and judgment.~~
~~(f) Curriculum Content.~~
~~(1) Areas of didactic and laboratory instruction shall include at least the following areas and shall be related specifically to extended functions:~~
~~(A) Biomedical - nutrition and preventive dentistry.~~
~~(B) Dental science - materials, oral anatomy and physiology, oral pathology, pharmacology, morphology, microbiology, and histology.~~
~~(C) Dental assisting - general and special dentistry, legal/ethical aspects of dentistry, and patient/dental personnel psychology.~~
~~(D) Emergency procedures.~~
~~(E) Coronal polishing in pit and fissure sealant procedures. (2) A student who possesses a valid certificate in coronal polishing need not take any course in coronal polishing in order to complete the program.~~
~~(3) Each student shall be provided, as part of an organized program of instruction, with sufficient clinical experience to obtain competency in all functions approved by the board for performance by an RDAEF.~~
~~(g) Length of Program. The program shall be not less than 90 hours in length and shall be of sufficient length, as determined by the dental school faculty, to ensure that all students will possess the necessary skills to consistently perform extended functions safely on a patient. The board shall reevaluate the minimum length of the program one year after the effective date of this rule.~~

~~Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1756, Business and Professions Code.~~

(a) A new educational program for RDAEF's shall apply for and receive approval prior to operation. The Board may approve, provisionally approve, or deny approval of any such program. The Board may, in lieu of conducting its own investigation, accept the findings of any commission or accreditation agency approved by the Board and adopt those findings as its own.

(~~a~~b) In addition to the requirements of Sections 1070 and 1070.1, the following criteria shall be met by an educational program for registered dental assistants in extended functions (RDAEF) to secure and maintain approval by the board.

(1) A program applying for approval to teach all of the duties specified in Section 1753.5 shall comply with all of the requirements of this section.

(2) A program applying for approval to teach RDAEFs licensed on or before January 1, 2010 the additional duties specified in Section 1753.6 shall comply with all of the requirements of this section, except as follows:

(A) The program shall be no less than ~~288~~ ***320*** hours, including at least 76 hours of didactic instruction, at least ~~180~~ ***186*** hours of laboratory instruction, and at least ~~32~~ ***58*** hours of clinical instruction.

(B) Students shall not be required to complete instruction related to the placement of gingival retraction cord, the taking of final impressions for permanent indirect restorations, or the fitting of endodontic master ***points*** and accessory points.

(~~b~~c) In order to be admitted to the program, each student shall possess a valid, active, and current license as a registered dental assistant issued by the board and shall submit documentary evidence of successful completion of a board-approved pit and fissure sealant course.

(~~c~~d) ~~Adequate provision for the supervision and operation of the program shall be made in compliance with section 1070. Notwithstanding the requirements of Sections 1070 and 1070.1, the program director and each faculty member of an approved RDAEF program shall possess a valid, active, and current license as a dentist or an RDAEF.~~ In addition to the requirements of Sections 1070 and 1070.1, all faculty members responsible for clinical evaluation shall have completed a ~~six-hour teaching methodology course in clinical evaluation prior to conducting clinical evaluations of students~~ ***Board-approved*** course or certification program in educational methodology of at least six (6) hours by January 1, 2012, unless he or she holds any one of the following: a postgraduate degree in education, a Ryan Designated Subjects Vocational Education Teaching Credential, a Standard Designated Subjects Teaching Credential, or, a Community College Teaching Credential. Each faculty member employed on or after January 1, 2012, shall complete a course or certification program in educational methodology within six months of employment. The program director or designated administrator shall be responsible to obtain and maintain records of each faculty member showing evidence of having met this regulation.

(~~d~~e) The program shall be of sufficient duration for the student to develop minimum competence in all of the duties that RDAEFs are authorized to perform, but in no event less than ~~380~~ ***412*** hours, including at least 100 hours of didactic instruction, at least ~~200~~ ***206*** hours of laboratory instruction, and at least ~~80~~ ***106*** hours of clinical instruction. All laboratory and simulated clinical instruction shall be provided under the direct supervision of program staff. Clinical instruction shall be provided under the direct supervision of a licensed dentist and may be completed in an extramural dental facility as defined in Section 1070.1(i).

(~~e~~f) The following requirements are in addition to the requirements of Sections 1070 and 1070.1:

(1) The following are minimum requirements for e~~E~~quipment and armamentaria:

(A) Laboratory facilities with individual seating stations for each student and equipped with air, gas and air, or electric driven rotary instrumentation capability. Each station or operatory shall allow an articulated typodont to be mounted in a simulated head position.

(B) Clinical simulation facilities that provide simulated patient heads mounted in appropriate position and accommodating an articulated typodont in an enclosed intraoral environment, or mounted on a dental chair in a dental operatory. Clinical simulation spaces shall be sufficient to permit one simulation space for each two students at any one time.

(C) Articulated typodonts of both deciduous and permanent dentitions with flexible gingival tissues and with prepared teeth for each procedure to be performed in the laboratory and clinical simulation settings. One of each type of typodont is required for each student.

(D) A selection of restorative instruments and adjunct materials for all procedures that RDAEFs are authorized to perform.

(2) Notwithstanding Section 1070, there shall be at least one operatory for every two students who are simultaneously engaged in clinical instruction.

(~~f~~g) Areas of instruction shall include, at a minimum, the instruction specified in subdivisions (g) to (m), inclusive, and the following didactic instruction:

(1) The following instruction as it relates to each of the procedures that RDAEFs are authorized to perform: restorative and prosthetic treatment review; charting; patient education; legal requirements; indications and contraindications; problem solving techniques; laboratory, preclinical, and clinical criteria and evaluation; and infection control protocol implementation.

(2) Dental science, including dental and oral anatomy, histology, oral pathology, normal or abnormal anatomical and physiological tooth descriptions, tooth morphology, basic microbiology relating to infection control, and occlusion.

(3) Characteristics and manipulation of dental materials related to each procedure.

(4) Armamentaria for all procedures.

(5) Principles, techniques, criteria, and evaluation for performing each procedure, including implementation of infection control protocols.

(6) Occlusion: the review of articulation of maxillary and mandibular arches in maximum intercuspation.

(7) Tooth isolation and matrix methodology review.

(~~g~~h) General laboratory instruction shall include:

(1) Rubber dam application for tooth isolation in both maxillary and mandibular arches and for deciduous and permanent dentitions. A minimum of four experiences per arch is required, with two anterior and two posterior applications, with one of the applications used for a practical examination.

(2) Matrix placement for amalgam, and nonmetallic restorative material restorations in both primary and permanent dentitions, with three experiences for each cavity classification and for each material.

(3) Base, liner, and etchant placement on three posterior teeth for each base, liner, or etchant, with one of the three teeth used for a practical examination.

(~~h~~i) With respect to preliminary evaluation of the patient's oral health, including, ~~at a minimum,~~ charting of existing conditions excluding periodontal assessment, intraoral and extraoral evaluation of soft tissue, classifying occlusion, and myofunctional evaluation:

(1) Didactic instruction shall contain the following:

(A) Normal anatomical structures: oral cavity proper, vestibule, and lips.

(B) Deviations from normal to hard tissue abnormalities to soft tissue abnormalities.

(C) Overview of classifications of occlusion and myofunction.

(D) Sequence of oral inspection: armamentaria, general patient assessment, review of medical history form, review of dental history form, oral cavity mouth-mirror inspection, and charting existing conditions.

(2) Preclinical instruction shall include performing an oral inspection on at least two other students.

(3) Clinical instruction shall include performing an oral inspection on at least two patients, with one of the two patients used for a clinical examination.

(~~i~~j) With respect to sizing, fitting, and cementing endodontic master points and accessory points:

(1) Didactic instruction shall include the following:

(A) Review of objectives, canal preparation, filling of root canal space, including the role of the RDAEF as preparatory to condensation which is to be performed by the licensed dentist.

(B) Description and goals of filling technique using lateral condensation techniques.

(C) Principles and techniques of fitting~~,~~ ***and*** cementing master ***points*** and accessory points using lateral condensation including, characteristics, manipulation, use of gutta percha and related materials, and criteria for an acceptable master and accessory points technique using lateral condensation.

(2) Laboratory instruction shall include fitting ***and cementing*** master ***points and accessory points*** ~~***and cementing cones***~~ on extracted teeth or ~~assimilated~~ simulated teeth with canals in preparation for lateral condensation by the dentist, with at a minimum two experiences each on a posterior and anterior tooth. This instruction shall not include obturator based techniques or other techniques that employ condensation.

(3) Simulated clinical instruction shall include fitting~~,~~ ***and*** cementing master ***points*** and accessory points in preparation for condensation by the dentist with extracted or simulated teeth prepared for lateral condensation mounted in simulated patient heads mounted in appropriate position and accommodating and articulated typodont in an enclosed intraoral environment, or mounted on a dental chair in a dental operatory. This instruction shall not include obturator based techniques that employ condensation. Simulated clinical instruction shall include fitting ***and cementing*** master ***points*** ~~***cones***~~ and accessory points for lateral condensation by the dentist in at least four teeth, one of which shall be used for a practical exam.

(~~j~~k) With respect to gingival retraction, general instruction shall include:

(1) Review of characteristics of tissue management as it relates to gingival retraction with cord and electrosurgery.

(2) Description and goals of cord retraction.

(3) Principles of cord retraction, including characteristics and manipulation of epinephrine, chemical salts classification of cord, characteristics of single versus double cord technique, and techniques and criteria for an acceptable cord retraction technique.

(~~k~~l) With respect to final impressions for permanent indirect and toothborne restorations:

(1) Didactic instruction shall contain the following:

(A) Review of characteristics of impression material and custom.

(B) Description and goals of impression taking for permanent indirect restorations and toothborne prosthesis.

(C) Principles, techniques, criteria, and evaluation of impression taking for permanent indirect restorations and toothborne prosthesis.

(2) Laboratory instruction shall include the following:

(A) Cord retraction and final impressions for permanent indirect restorations, including impression taking of prepared teeth in maxillary and mandibular arches, one time per arch with elastomeric impression materials.

(B) Impressions for toothborne removable prostheses, including, at a minimum, taking a total of four impressions on maxillary and mandibular arches with simulated edentulous sites and rest preparations on at least two supporting teeth in each arch.

(3) Clinical instruction shall include taking final impressions on five cord retraction patients, with one used for a clinical examination.

(~~l~~m) With respect to placing, contouring, finishing, and adjusting direct restorations:

(1) Didactic instruction shall contain the following:

(A) Review of cavity preparation factors and restorative material.

(B) Review of cavity liner, sedative, and insulating bases.

(C) Characteristics and manipulation of direct filling materials.

(D) Amalgam restoration placement, carving, adjusting and finishing, which includes principles, techniques, criteria and evaluation, and description and goals of amalgam placement, adjusting and finishing in children and adults.

(E) Glass-ionomer restoration placement, carving, adjusting, contouring and finishing, which includes, principles, techniques, criteria and evaluation, and description and goals of glass-ionomer placement and contouring in children and adults.

(F) Composite restoration placement, carving, adjusting, contouring and finishing in all cavity classifications, which includes, principles, techniques, criteria, and evaluation.

(2) Laboratory instruction shall include typodont experience on the following:

(A) Placement of Class I, II, and V amalgam restorations in eight prepared permanent teeth for each classification, and in four deciduous teeth for each classification.

(B) Placement of Class I, II, III, and V composite resin restorations in eight prepared permanent teeth for each classification, and in four deciduous teeth for each classification.

(C) Placement of Class I, II, III, and V glass-ionomer restorations in four prepared permanent teeth for each classification, and in four deciduous teeth for each classification.

(3) ~~Clinical simulation and~~ Simulated clinical instruction shall include experience with typodonts mounted in simulated heads on a dental chair or in a simulation laboratory as follows:

(A) Placement of Class I, II, and V amalgam restorations in four prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(B) Placement of Class I, II, III, and V composite resin restorations in four prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(C) Placement of Class I, II, III, and V glass-ionomer restorations in four prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(4) Clinical instruction shall ~~***include experience with the following techniques***~~ ***require proficient completion of placing, contouring and finishing at least twenty (20) direct restorations in prepared permanent teeth with the following requirements***:

~~***(A) Placement of Class I, II, and V amalgam restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.***~~

~~***(B) Placement of Class I, II, III, and V composite resin restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.***~~

~~*(C) Placement of Class I, II, III, and V glass-ionomer restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.*~~

(A) At least fifty (50) percent of the experiences shall be Class II restorations using esthetic materials.

(B) At least twenty (20) percent of the experiences shall be Class V restorations using esthetic materials.

(C) At least ten (10) percent of the experiences shall use amalgam.

(D) Students who complete the 20 restorations and meet all the instructional requirements of this section may complete additional Class I,II,III or V restorations as deemed appropriate for program success.

(~~m~~n) With respect to polishing and contouring existing amalgam restorations:

(1) Didactic instruction shall include principles, techniques, criteria and evaluation, and description and goals of amalgam polishing and contouring in children and adults.

(2) Laboratory instruction shall include typodont experience on polishing and contouring of Class I, II, and V amalgam restorations in three prepared permanent teeth for each classification, and in two deciduous teeth for each classification.

(3) ~~Clinical simulation and~~ Simulated clinical instruction shall include experience with typodonts mounted in simulated heads on a dental chair or in a simulation laboratory in the polishing and contouring of Class I, II, and V amalgam restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(~~n~~o) With respect to adjusting and cementing permanent indirect restorations:

(1) Didactic instruction shall contain the following:

(A) Review of fixed prosthodontics related to classification and materials for permanent indirect restorations, general crown preparation for permanent indirect restorations, and laboratory fabrication of permanent indirect restorations.

(B) Interocclusal registrations for fixed prosthesis, including principles, techniques, criteria, and evaluation.

(C) Permanent indirect restoration placement, adjustment, and cementation, including principles, techniques, criteria, and evaluation.

(2) Laboratory instruction shall include:

(A) Interocclusal registrations using elastomeric and resin materials. Two experiences with each material are required.

(B) Fitting, adjustment, and cementation of permanent indirect restorations on one anterior and one posterior tooth for each of the following materials, with one of each type used for a practical examination: ceramic, ceramometal, and cast metallic.

(3) Clinical experience for interocclusal registrations shall be performed on four patients who are concurrently having final impressions recorded for permanent indirect restorations, with one experience used for a clinical examination.

(4) Clinical instruction shall include fitting, ~~***and***~~ adjustment, and cementation of permanent indirect restorations on at least ***two teeth~~one anterior and one posterior tooth for each of the following materials, with one of each type used for a clinical examination: ceramic, ceramometal, and cast metallic~~***.

(~~e~~p) 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.

(q) 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 Registered Dental Assistant in Extended Functions Educational Programs (New 10/10)" within ninety (90) days of the effective date of these regulations.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1753, Business and Professions Code.

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
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NOTICE OF COMPLIANCE WITH NEW REQUIREMENTS FOR REGISTERED DENTAL ASSISTANT EDUCATIONAL PROGRAMS

To maintain approval by the Board, each Registered Dental Assistant (RDA) educational program that was approved prior to the date that Sections 1070 and 1070.2 became effective must complete and submit this form to the Board at its offices no later than 90 days from the effective date of these new requirements. Any student graduating from such a program will not be accepted to sit for examination or qualify for registration until this form has been submitted to the Board.

I, _____ *Enter Name*),

Program Director for _____ *(Enter Full Name of Educational Institution or Program)* **HEREBY CERTIFY:**

1) **I have read the attached regulations pertaining to the approval of Registered Dental Assistant (RDA) educational programs, including Sections 1070 and 1070.2 of Title 16 of the California Code of Regulations;**

2) **I have the authority to sign this notice on behalf of the educational institution or program; and,**

3) **That to the best of my knowledge, information and belief, the institution and its RDA programs or courses comply with these regulations and have been in compliance with these regulations since** _____ *(Insert Date)*.

I certify under penalty of perjury under the laws of the State of California that this Notice of Compliance is true and correct.

_____

Signature of Program Director **DATE**

Printed Name of Program Director: _____

Name of Educational Institution or Program: _____

Address of Educational Institution or Program: _____

Telephone Number: _____ **Email Address:** _____

NOTICE OF COLLECTION OF PERSONAL INFORMATION

Disclosure of your personal information is mandatory. The information on this application is required pursuant to Title 16, California Code of Regulations Sections 1070, 1070.2. Failure to provide any of the required information will result in the form being rejected as incomplete and your approval may be withdrawn for noncompliance. The information provided will be used to determine compliance with Article 2 of Division 10 of Title 16 of the California Code of Regulations (beginning at Section 1070). The information collected may be transferred to other governmental and enforcement agencies. Individuals have a right of access to records containing personal information pertaining to that individual that are maintained by the Board, unless the records are exempted from disclosure by Section 1798.40 of the Civil Code. Individuals may obtain information regarding the location of his or her records by contacting the Executive Officer at the Board at the address and telephone number listed above.

REGULATIONS PERTAINING TO THE APPROVAL OF REGISTERED DENTAL ASSISTANT EDUCATIONAL PROGRAMS

Title 16 of the California Code of Regulations

Section 1070. General Provisions Governing All Dental Assistant Educational Programs and Courses.

(a) (1) The criteria in subdivisions (b) to (h), inclusive, shall be met by a dental assisting program or course and all orthodontic assisting and dental sedation assisting permit programs or courses to secure and maintain approval by the board as provided in this article.

(2) The board may approve, provisionally approve, or deny approval of any program or course for which an application to the Board for approval is required. All RDA and RDAEF programs and dental assisting educational courses shall be re-evaluated approximately every seven years, but may be subject to re-evaluation and inspection by the Board at any time to review and investigate compliance with this article and the Act. Re-evaluation may include a site visit or written documentation that ensures compliance with all regulations. Results of re-evaluation shall be reported to the Board or its designee for final consideration and continuance of program or course approval, provisional approval and denial of approval.

(3) Program and course records shall be subject to inspection by the board at any time.

(4) The board may withdraw approval at any time that it determines that a program or course does not meet the requirements of this article or any other requirement in the Act.

(5) All programs and courses shall be established at the postsecondary educational level or deemed equivalent thereto by the board.

(6) The Board or its designee may approve, provisionally approve, or deny approval to any such program. Provisional approval shall not be granted for a period which exceeds beyond the length of the program. When the Board provisionally approves a program, it shall state the reasons therefore. Provisional approval shall be limited to those programs which substantially comply with all existing standards for full approval. A program given provisional approval shall immediately notify each student of such status. If the Board denies approval of a program, the specific reasons therefore shall be provided to the program by the Board in writing within 90 days after such action.

(b) The program or course director shall possess a valid, active, and current license issued by the board or the dental hygiene committee. The program or course director shall actively participate in and be responsible for the administration of the program or course. Specifically, the program or course director shall be responsible for the following requirements:

(1) Maintaining for a period of not less than five years copies of curricula, program outlines, objectives, and grading criteria, and copies of faculty credentials, licenses, and certifications, and individual student records, including those necessary to establish satisfactory completion of the program or course.

(2) Informing the board of any major change to the program or course content, physical facilities, or faculty, within 10 days of the change.

(3) Ensuring that all staff and faculty involved in clinical instruction meet the requirements set forth in this article.

(c) Course faculty and instructional staff shall be authorized to provide instruction by the program or course director and the educational facility in which instruction is provided.

(d) No faculty or instructional staff member shall instruct in any procedure that he or she does not hold a license or permit in California to perform. Each faculty or instructional staff member shall possess a valid, active, and current license issued by the Board or the Dental Hygiene Committee of California, shall have been licensed or permitted for a minimum of two years and possess experience in the subject matter he or she is teaching. An instructor who has held a license as a registered dental assistant or registered dental assistant in extended functions for at least two years, who then becomes a permit holder as an Orthodontic Assistant on or after January 1, 2010 shall not be required to have held such a permit for two years in order to instruct in the subject area.

(e) A certificate, diploma, or other evidence of completion shall be issued to each student who successfully completes the program or course and shall include the following: the student's name, the name of the program or course, the date of completion, and the signature of the program or course director or his or her designee.

(f) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties for which the program or course is approved to instruct.

(1) The location and number of general use equipment and armamentaria shall ensure that each student has the access necessary to develop minimum competency in all of the duties for which the program or course is approved to instruct. The program or course provider may either provide the specified equipment and supplies or require that the student provide them. Nothing in this section shall preclude a dental office that contains the equipment required by this section from serving as a location for laboratory instruction.

(2) Clinical instruction shall be of sufficient duration to allow the procedures to be performed to clinical proficiency. Operatories shall be sufficient in number to allow a ratio of at least one operatory for every five students who are simultaneously engaged in clinical instruction.

(A) Each operatory shall contain functional equipment, including a power-operated chair for patient or simulation-based instruction in a supine position, operator and assistant stools, air-water syringe, adjustable light, oral evacuation equipment, work surface, handpiece connection, and adjacent hand-washing sink.

(B) Each operatory shall be of sufficient size to simultaneously accommodate one student, one instructor, and one patient or student partner.
(C) Prior to clinical assignments, students must demonstrate minimum competence in laboratory or preclinical performance of the procedures they will be expected to perform in their clinical experiences.

(g) The program or course shall establish written clinical and laboratory protocols that comply with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. The program or course shall provide these protocols to all students, faculty, and instructional staff to ensure compliance. Adequate space shall be provided for handling, processing and sterilizing all armamentarium.

(h) A written policy on managing emergency situations shall be made available to all students, faculty, and instructional staff. All faculty and staff involved in the direct oversight of patient care activities shall be certified in basic life support procedures, including cardiopulmonary resuscitation. Recertification intervals may not exceed two years. The program or course director shall ensure and document compliance by faculty and instructional staff. A program or course shall sequence curriculum in such a manner so as to ensure that students complete instruction in basic life support prior to performing procedures on patients used for clinical instruction and evaluation.

(i) A detailed program or course outline shall clearly state, in writing, the curriculum subject matter, hours of didactic, laboratory, and clinical instruction, general program or course objectives, instructional objectives, theoretical content of each subject, and, where applicable, the use of practical application. Objective evaluation criteria shall be used for measuring student progress toward attainment of specific program or course objectives. Students shall be provided with all of the following:

(1) Specific performance objectives and the evaluation criteria used for measuring levels of competence for each component of a given procedure including those used for examinations.
(2) Standards of performance that state the minimum number of satisfactory performances that are required for each performance-evaluated procedure.
(3) Standards of performance for laboratory, preclinical, and clinical functions, those steps that would cause the student to fail the task being evaluated, a description of each of the grades that may be utilized during evaluation procedures, and a defined standard of performance.

(j) (1) As used in this article "extramural dental facility" means any clinical facility employed by an approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary campus of the approved program and in which dental treatment is rendered.
(2) If an extramural dental facility is utilized, students shall, as part of an extramural organized program of instruction, be provided with planned, supervised clinical instruction. Laboratory and preclinical instruction shall be performed under the direct supervision of program or course faculty or instructional staff and shall not be provided in an extramural dental facility.
(3) The program or course director, or a designated faculty member, shall be responsible for selecting extramural clinical sites and evaluating student competence before and after the clinical assignment.
(4) Prior to student assignment in an extramural dental facility, the program or course director, or a designated faculty or instructional staff member, shall orient dentists and all licensed dental healthcare workers who may provide instruction, evaluation and oversight of the student in the clinical setting. Orientation shall include, at a minimum, the objectives of the program or course, the student's preparation for the clinical assignment, and a review of procedures and criteria to be used by the dentist or the licensed personnel in the extramural dental facility in evaluating the student during the assignment, which shall be the same as the evaluation criteria used within the program or course.
(5) There shall be a written contract of affiliation between the program and each extramural dental facility that includes written affirmation of compliance with the regulations of this Article

Section 1070.2. Approval of Registered Dental Assistant Educational Programs

(a) All Registered Dental Assistant programs in California shall apply for and receive board approval prior to operation.

(b) The Board may, in lieu of conducting its own investigation, accept the findings of any commission or accreditation agency approved by the Board and adopt those findings as its own. All programs accredited by the American Dental Association Commission on Dental Accreditation (Commission) shall submit to the Board after each site visit a copy of the final report of the Commission's findings within 30 days of the final report issuance. New programs approved by the Commission shall apply to the Board and shall submit proof of Provisional Approval status by the Commission, a copy of the institutional self study and applications for Radiation Safety, Coronal Polish, Pit and Fissure Sealants and any other courses required of an RDA educational program. Acceptance of the Commission's or any accrediting agencies' findings is at the discretion of the Board and does not prohibit the Board from exercising its right to site evaluate a program.

(c) If the program is granted the status of "Approved with Reporting Requirements" from the Commission, the program shall submit to the Board copies of any and all correspondence received from or submitted to the Commission until such time as the status of "Approval without Reporting Requirements" is granted. Additionally, if the program withdraws from accredited status by the Commission, the program shall notify the Board, in writing, of such status within 30 days.

(d) In order for a registered dental assistant program to secure and maintain approval by the board, it shall meet the requirements of sections 1070 and 1070.1 and the requirements contained in this section.

(1) A program shall notify the board in writing if it wishes to increase the maximum student enrollment for which it is approved and shall provide documentation to the board to demonstrate compliance with Section 1070 and Section 1070.1 to reapprove the program for the increased enrollment prior to accepting additional students.
(2) Programs shall establish and maintain an advisory committee whose membership provides for equal representation of dentists and dental assistants, all currently licensed by the board. In addition, consideration shall be given to a student, a recent graduate or a public representative to serve on the advisory committee. The advisory committee shall meet at least once each academic year with the program director, faculty, and appropriate institutional personnel to monitor the ongoing quality and performance of the program and to receive advice and assistance from the committee.
(3) Adequate provision for the supervision and operation of the program shall be made. In addition to the requirements of sections 1070 and 1070.1, the following requirements shall be met:

(A) By January 1, 2012, each faculty member shall have completed a course or certification program in educational methodology of at least 30 hours, unless he or she holds any one of the following: a postgraduate degree in education, a Ryan Designated Subjects Vocational Education Teaching Credential, a Standard Designated Subjects Teaching Credential, or, a Community College Teaching Credential. Each faculty member employed after January 1, 2012, shall complete a course or certification program in educational methodology within six months of employment. The program director or designated administrator shall be responsible to obtain and maintain records of each faculty member showing evidence of having met this regulation.

(B) The program director shall have teaching responsibilities that are less than those of a full-time faculty member. He or she shall actively participate in and be responsible for the administration of the program including the following:

(i) Participating in budget preparation and fiscal administration, curriculum development and coordination, determination of teaching assignments, supervision and evaluation of faculty, establishment of criteria and procedures, design and operation of program facilities, and selection of extramural facilities and coordination of instruction in those facilities.

(ii) Holding periodic staff meetings to provide for subject matter review, instructional calibration, curriculum evaluation, and coordinating activities of full-time, part-time, and volunteer faculty or instructional staff.

(iii) Maintaining for not less than five years' copies of minutes of all advisory committee and staff meetings.

(C) The owner or school administrator shall be responsible for the compliance of the program director with the provisions of this section and Sections 1070 and 1070.1.

(4) The program shall have sufficient financial resources available to support the program and to comply with this section. If the program or school requires approval by any other governmental agency, that approval shall be obtained prior to application to the board for approval and shall be maintained at all times. The failure to maintain that approval shall result in the automatic withdrawal of board approval of the program.
(5) The program shall be of sufficient duration for the student to develop minimum competence in performing dental assistant and registered dental assistant duties, but in no event less than 800 hours, including at least 275 hours of didactic instruction, at least 260 hours of combined laboratory or preclinical instruction conducted in the program's facilities under the direct supervision of program faculty or instructional staff, and the remaining hours utilized in clinical instruction in extramural dental facilities. No more than 20 hours of instruction shall be devoted to clerical, administrative, practice management, or similar duties. Programs whose demonstrated total hours exceed 800 and who meet all the instructional requirements in this section, may utilize the additional instructional hours as deemed appropriate for program success. 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 Registered Dental Assistant Educational Programs (New 9/10)" within ninety (90) days of the effective date of these regulations.
(6) In addition to the requirements of Section 1070 with regard to extramural instruction:

(A) No more than 25 percent of extramural clinical instruction shall take place in a specialty dental practice.

(B) Program faculty shall visit each extramural clinical facility at least once every ten clinical days.

(7) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties that registered dental assistants are authorized to perform. The following requirements are in addition to those contained in Sections 1070 and 1070.1:

(A) The following are minimum requirements for equipment and armamentaria during laboratory, preclinical, and clinical sessions as appropriate to each type of session: amalgamator, model trimmers in the ratio of one for every seven students, dental rotary equipment in the ratio of one for every three students, vibrators in the ratio of one for every three students, light curing devices in the ratio of one for every operatory, functional typodonts and bench mounts in the ratio of one for every two students, functional orthodontically banded typodonts in the ratio of one for every four students, facebows in the ratio of one for every ten students, automated blood pressure device, EKG machine, pulse oximeters in the ratio of one for every ten students, capnograph or simulated device, one sets of hand instruments in the ratio of one set for every two students for each procedure, respiration device, camera for intraoral use, camera for extraoral use, CAD machine or simulated device, caries detection device in the ratio of one for every ten students, and all other equipment and armamentaria required to teach dental assistant and registered dental assistant duties. With

the exception of patient monitoring equipment specific to EKG machine and pulse oximeter, the program shall own the necessary equipment and have it readily available upon inspection. Patient monitoring equipment owned by the institution and utilized by more than one program within the institution premises is acceptable and may be used by the RDA program as needed for instruction. Instruction by a licensed healthcare provider is acceptable. In the event instruction in patient monitoring procedures is provided by an outside provider, the RDA program shall not be required to have available or own patient monitoring equipment.

(B) Instruments must be provided to accommodate students needs in learning to identify, exchange, prepare procedural trays and assist in procedures as they relate to general and specialty dentistry.

(C) Provision shall be made for reasonable access to current and diverse dental and medical reference texts, current journals, audiovisual materials, and other necessary resources. Library holdings, which may include, in total or in part, access through the Internet, shall include materials relating to all subject areas of the program curriculum.

(D) Emergency materials shall include, at a minimum, an oxygen tank that is readily available and functional. Medical materials for treating patients with life-threatening conditions shall be available for instruction and accessible to the operatories. Facilities that do not treat patients shall maintain a working model of a kit of such emergency materials for instructional purposes.

(8) Curriculum documentation shall be reviewed annually and revised, as needed, to reflect new concepts and techniques. This content must be integrated and of sufficient depth, scope, sequence of instruction, quality and emphasis to ensure achievement of the curriculum's defined competencies.

(A) Programs that admit students in phases, including modular or open-entry programs, shall provide, at minimum, basic instruction in tooth anatomy, tooth numbering, general program guidelines, basic chairside skills, emergency and safety precautions, infection control and sterilization protocols associated with and required for patient treatment. Such instruction shall occur prior to any other program content and prior to performances or activities involving patients.

(B) All programs shall provide students with additional instruction in the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 prior to the student's performance of procedures on patients.

(9) In addition to the requirements of Sections 1070 and 1070.1 and subdivisions (b) (11) and (b) (12) of this section, programs shall include the following content:

(A) Instruction in radiation safety that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 1, Article 3.1, Sections 1014 and 1014.1.

(B) Instruction in coronal polishing that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.4.

(C) Instruction in the application of Pit and Fissure Sealants that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.3.

(D) A course in basic life support provided by an instructor approved by the American Red Cross or the American Heart Association, or any other course approved by the board as equivalent. The program may require that the student complete this course as a prerequisite to program enrollment, or that the student provide evidence of having completed the course from another provider.

(E) Instruction in infection control that meets all of the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.6.

(F) Instruction in the Dental Practice Act that includes the content specified in the California Code of Regulations, Title 16, Division 10, Chapter 1, Article 4, Section 1016 governing Dental Practice Act continuing education courses.

(10) A program that desires to provide instruction in the following areas shall apply separately for approval to provide the following courses:

(A) A course in the removal of excess cement with an ultrasonic scaler, which course shall meet the requirements of California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.5.

(B) An orthodontic assistant permit course that shall meet the requirements of California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.7, except that a program shall not be required to obtain separate approval to teach the duties of placing ligature ties and archwires, removing orthodontic bands, and removing excess cement from surfaces of teeth with a hand instrument, and shall be no less than 60 hours, including at least 12 hours of didactic instruction, at least 26 hours of laboratory instruction, and at least 22 hours of clinical instruction.

(C) A dental sedation assistant permit course that shall meet the requirements of the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.8.

(D) A Registered Dental Assisting educational program that includes instructional content for either the orthodontic assistant permit or dental sedation assistant permit or both, shall provide a certificate or certificates of completion to the graduate. The certificate holder shall be deemed an eligible candidate for the permit examination process as having met all educational requirements for the permit examination.

(11) General didactic instruction shall include, at a minimum, the following:

(A) Principles of general anatomy, physiology, oral embryology, tooth histology, and head-neck anatomy.
(B) Principles of conditions related to and including oral pathology, orthodontics, periodontics, endodontics, pediatric dentistry, oral surgery, prosthodontics, and esthetic dentistry.
(C) Instruction in the Dental Practice Act that includes the content specified in the California Code of Regulations, Title 16, Division 10, Chapter 1, Article 4, Section 1016, as well as principles of HIPAA privacy and security standards, risk management and professional codes of ethical behavior.
(D) Principles of infection control, waste management and hazardous communication requirements in compliance with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. Instruction in infection control shall meet the education requirements set forth in Section 1070.6(e).
(E) Principles related to pharmacology and biomedical sciences including nutrition and microbiology.
(F) Principles of medical-dental emergencies and first aid management.
(G) Principles of the treatment planning process including medical health history data collection, patient and staff confidentiality, and charting.
(H) Principles of record classifications including management, storage, and retention protocol for all dental records including the legal and ethical issues involving patient records.
(I) Principles and protocols of special needs patient management, the psychology and management of dental patients, and overall interpersonal relationships.
(J) Principles, protocols, and armamentaria associated with all dental assisting chairside procedures.
(K) Principles, protocols, manipulation, use, and armamentaria for contemporary dental materials used in general and specialty dentistry.
(L) Principles and protocols for oral hygiene preventative methods including, plaque identification, toothbrushing and flossing techniques, and nutrition.
(M) Principles, protocols, armamentaria, and procedures associated with operative and specialty dentistry.
(N) Principles, protocols, armamentaria, and procedures for each duty that dental assistants and registered dental assistants are allowed to perform.
(O) All content for instruction in radiation safety as set forth in California Code of Regulations, Title 16, Division 10, Chapter 1, Article 3.1, Section 1014.1.
(P) All content for instruction in coronal polishing as set forth in California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.4.
(Q) All content for instruction in the application of Pit and Fissure Sealants as set forth in California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.3.

(12) Laboratory and clinical instruction shall be of sufficient duration and content for each student to achieve minimum competence in the performance of each procedure that dental assistant and registered dental assistant is authorized to perform.
(13) 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.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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NOTICE OF COMPLIANCE WITH NEW REQUIREMENTS FOR INFECTION CONTROL COURSES

To maintain approval by the Board, each Infection Control Course that was approved prior to the date that Sections 1070, 1070.1 and 1070.6 became effective must complete and submit this form to the Board at its offices no later than 90 days from the effective date of these new requirements. Any student graduating from such a course will not be accepted to sit for examination or qualify for registration until this form has been submitted to the Board. Certificates of Completion issued by educational course providers not meeting Notice submission requirements will not be recognized by the Board.

I, _____ *Enter Name*),

Course Provider for _____ *Enter Full Name of Educational Institution, Organization, or Course Provider*) **HEREBY CERTIFY:**

1) **I have read the attached regulations pertaining to the approval of Infection Control Courses, including Sections 1070, 1070.1 and 1070.6 of Title 16 of the California Code of Regulations;**

2) **I have the authority to sign this notice on behalf of the educational institution, organization, or course provider; and,**

3) **That to the best of my knowledge, information and belief, the institution, organization, or course provider and its programs or courses comply with these regulations and have been in compliance with these regulations since** _____ (*Insert Date*).

I certify under penalty of perjury under the laws of the State of California that this Notice of Compliance is true and correct.

_____

Signature of Course Provider **DATE**

Printed Name of Course Provider: _____

Name of Educational Institution, Organization, or Course Provider:

_____

Address of Educational Institution, Organization, or Course Provider:

_____

Telephone Number: _____ **Email Address:** _____

NOTICE OF COLLECTION OF PERSONAL INFORMATION

Disclosure of your personal information is mandatory. The information on this application is required pursuant to Title 16, California Code of Regulations Sections 1070, 1070.6. Failure to provide any of the required information will result in the form being rejected as incomplete and your approval may be withdrawn for noncompliance. The information provided will be used to determine compliance with Article 2 of Division 10 of Title 16 of the California Code of Regulations (beginning at Section 1070). The information collected may be transferred to other governmental and enforcement agencies. Individuals have a right of access to records containing personal information pertaining to that individual that are maintained by the Board, unless the records are exempted from disclosure by Section 1798.40 of the Civil Code. Individuals may obtain information regarding the location of his or her records by contacting the Executive Officer at the Board at the address and telephone number listed above.

REGULATIONS PERTAINING TO THE APPROVAL OF INFECTION CONTROL COURSES

Title 16 of the California Code of Regulations

Section 1070. General Provisions Governing All Dental Assistant Educational Programs and Courses.

(a) (1) The criteria in subdivisions (b) to (h), inclusive, shall be met by a dental assisting program or course and all orthodontic assisting and dental sedation assisting permit programs or courses to secure and maintain approval by the board as provided in this article.

(2) The board may approve, provisionally approve, or deny approval of any program or course for which an application to the Board for approval is required. All RDA and RDAEF programs and dental assisting educational courses shall be re-evaluated approximately every seven years, but may be subject to re-evaluation and inspection by the Board at any time to review and investigate compliance with this article and the Act. Re-evaluation may include a site visit or written documentation that ensures compliance with all regulations. Results of re-evaluation shall be reported to the Board or its designee for final consideration and continuance of program or course approval, provisional approval and denial of approval.

(3) Program and course records shall be subject to inspection by the board at any time.

(4) The board may withdraw approval at any time that it determines that a program or course does not meet the requirements of this article or any other requirement in the Act

(5) All programs and courses shall be established at the postsecondary educational level or deemed equivalent thereto by the board.

(6) The Board or its designee may approve, provisionally approve, or deny approval to any such program. Provisional approval shall not be granted for a period which exceeds beyond the length of the program. When the Board provisionally approves a program, it shall state the reasons therefore. Provisional approval shall be limited to those programs which substantially comply with all existing standards for full approval. A program given provisional approval shall immediately notify each student of such status. If the Board denies approval of a program, the specific reasons therefore shall be provided to the program by the Board in writing within 90 days after such action.

(b) The program or course director shall possess a valid, active, and current license issued by the board or the dental hygiene committee. The program or course director shall actively participate in and be responsible for the administration of the program or course. Specifically, the program or course director shall be responsible for the following requirements:

(1) Maintaining for a period of not less than five years copies of curricula, program outlines, objectives, and grading criteria, and copies of faculty credentials, licenses, and certifications, and individual student records, including those necessary to establish satisfactory completion of the program or course.

(2) Informing the board of any major change to the program or course content, physical facilities, or faculty, within 10 days of the change.

(3) Ensuring that all staff and faculty involved in clinical instruction meet the requirements set forth in this article.

(c) Course faculty and instructional staff shall be authorized to provide instruction by the program or course director and the educational facility in which instruction is provided.

(d) No faculty or instructional staff member shall instruct in any procedure that he or she does not hold a license or permit in California to perform. Each faculty or instructional staff member shall possess a valid, active, and current license issued by the Board of the Dental Hygiene Committee of California, shall have been licensed or permitted for a minimum of two years and possess experience in the subject matter he or she is teaching. An instructor who has held a license as a registered dental assistant or registered dental assistant in extended functions for at least two years, who then becomes a permit holder as an Orthodontic Assistant on or after January 1, 2010 shall not be required to have held such a permit for two years in order to instruct in the subject area.

(e) A certificate, diploma, or other evidence of completion shall be issued to each student who successfully completes the program or course and shall include the following: the student's name, the name of the program or course, the date of completion, and the signature of the program or course director or his or her designee.

(f) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties for which the program or course is approved to instruct.

(1) The location and number of general use equipment and armamentaria shall ensure that each student has the access necessary to develop minimum competency in all of the duties for which the program or course is approved to instruct. The program or course provider may either provide the specified equipment and supplies or require that the student provide them. Nothing in this section shall preclude a dental office that contains the equipment required by this section from serving as a location for laboratory instruction.

(2) Clinical instruction shall be of sufficient duration to allow the procedures to be performed to clinical proficiency. Operatories shall be sufficient in number to allow a ratio of at least one operatory for every five students who are simultaneously engaged in clinical instruction.

(A) Each operatory shall contain functional equipment, including a power-operated chair for patient or simulation-based instruction in a supine position, operator and assistant stools, air-water syringe, adjustable light, oral evacuation equipment, work surface, handpiece adaptation, and adjacent hand-washing sink

(B) Each operatory shall be of sufficient size to simultaneously accommodate one student, one instructor, and one patient or student partner.

(C) Prior to clinical assignments, students must demonstrate minimum competence in laboratory or preclinical performance of the procedures they will be expected to perform in their clinical experiences.

(g) The program or course shall establish written clinical and laboratory protocols that comply with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. The program or course shall provide these protocols to all students, faculty, and staff to ensure compliance. Adequate space shall be provided for handling, processing and sterilizing all armamentarium.

(h) A written policy on managing emergency situations shall be made available to all students, faculty, and instructional staff. All faculty and staff involved in the direct oversight of patient care activities shall be certified in basic life support procedures, including cardiopulmonary resuscitation. Recertification intervals may not exceed two years. The program or course director shall ensure and document compliance by faculty and instructional staff. A program or course shall sequence curriculum in such a manner so as to ensure that students complete instruction in basic life support prior to performing procedures on patients used for clinical instruction and evaluation.

(i) A detailed program or course outline shall clearly state, in writing, the curriculum subject matter, hours of didactic, laboratory, and clinical instruction, general program or course objectives, instructional objectives, theoretical content of each subject, and, where applicable, the use of practical application. Objective evaluation criteria shall be used for measuring student progress toward attainment of specific program or course objectives. Students shall be provided with all of the following:

(1) Specific performance objectives and the evaluation criteria used for measuring levels of competence for each component of a given procedure including those used for examinations.

(2) Standards of performance that state the minimum number of satisfactory performances that are required for each performance-evaluated procedure.

(3) Standards of performance for laboratory, preclinical, and clinical functions, those steps that would cause the student to fail the task being evaluated, a description of each of the grades that may be utilized during evaluation procedures, and a defined standard of performance.

(j) (1) As used in this article "extramural dental facility" means any clinical facility employed by an approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary campus of the approved program and in which dental treatment is rendered.

(2) If an extramural dental facility is utilized, students shall, as part of an extramural organized program of instruction, be provided with planned, supervised clinical instruction. Laboratory and preclinical instruction shall be performed under the direct supervision of program or course faculty or instructional staff and shall not be provided in an extramural dental facility.

(3) The program or course director, or a designated faculty member, shall be responsible for selecting extramural clinical sites and evaluating student competence before and after the clinical assignment.

(4) Prior to student assignment in an extramural dental facility, the program or course director, or a designated faculty or instructional staff member, shall orient dentists and all licensed dental healthcare workers who may provice instruction, evaluation and oversight of the student in the clinical setting. Orientation shall include, at a minimum, the objectives of the program or course, the student's preparation for the clinical assignment, and a review of procedures and criteria to be used by the dentist or the licensed personnel in the extramural dental facility in evaluating the student during the assignment, which shall be the same as the evaluation criteria used within the program or course.

(5) There shall be a written contract of affiliation between the program and each extramural dental facility that includes written affirmation of compliance with the regulations of this Article.

1070.6. Approval of Infection Control Courses

In addition to the requirements of Sections 1070 and 1070.1, the following criteria shall be met by a course in infection control, as required in Sections 1750, 1750.2, 1750.4, and 1752.1, to secure and maintain approval by the board:

(a) Adequate provisions for the supervision and operation of the course in infection control shall be made in compliance with Section 1070. Notwithstanding Section 1070, faculty shall not be required to be licensed by the board, but faculty shall have experience in the instruction of the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005. In addition, all faculty responsible for clinical evaluation shall have completed a two-hour methodology course in clinical evaluation.

(b) A course in infection control shall be of sufficient duration for the student to develop minimum competency in all aspects of the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005, but in no event less than eight hours, including at least four hours of didactic instruction, at least two hours of laboratory or preclinical instruction, and at least two hours of clinical instruction. Preclinical instruction shall utilize instruments, surfaces, and situations where contamination is simulated, without actual contamination, from bloodborne and other pathogens being present.

(c) The minimum requirements for equipment and armamentaria shall include personal protective equipment, FDA-approved sterilizer, ultrasonic unit or instrument processing device, sharps container, selection of instruments, equipment, and

armamentaria that are necessary to instruct or demonstrate proper hazardous waste disposal, consistent with the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2, local, state, and federal mandates, and all other armamentaria required to instruct or properly demonstrate the subjects described in the course content.

(d) Areas of instruction shall include, at a minimum, the instruction specified in subdivisions (e) and (f).

(e) Didactic instruction shall include, at a minimum, the following as they relate to the California Division of Occupational Safety and Health (Cal/OSHA) California Code of Regulations, Title 8, Division 1, Chapter 3.2 and the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005:

(1) Basic dental science and microbiology as they relate to infection control in dentistry.

(2) Legal and ethical aspects of infection control procedures.

(3) Terms and protocols specified in the California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 regarding the minimum standards for infection control.

(4) Principles of modes of disease transmission and prevention.

(5) Principles, techniques, and protocols of hand hygiene, personal protective equipment, surface barriers and disinfection, sterilization, sanitation, and hazardous chemicals associated with infection control.

(6) Principles and protocols of sterilizer monitoring and the proper loading, unloading, storage, and transportation of instruments to work area.

(7) Principles and protocols associated with sharps management.

(8) Principles and protocols of infection control for laboratory areas.

(9) Principles and protocols of waterline maintenance.

(10) Principles and protocols of regulated and nonregulated waste management.

(11) Principles and protocols related to injury and illness prevention, hazard communication, general office safety, exposure control, postexposure requirements, and monitoring systems for radiation safety and sterilization systems.

(f) Preclinical instruction shall include three experiences in the following areas, with one used for a practical examination:

(1) Apply hand cleansing products and perform hand cleansing techniques and protocols.

(2) Apply, remove, and dispose of patient treatment gloves, utility gloves, overgloves, protective eyewear, masks, and clinical attire.

(3) Apply the appropriate techniques and protocols for the preparation, sterilization, and storage of instruments including, at a minimum, application of personal protective equipment, precleaning, ultrasonic cleaning, rinsing, sterilization wrapping, internal or external process indicators, labeling, sterilization, drying, storage, and delivery to work area.

(4) Preclean and disinfect contaminated operatory surfaces and devices, and properly use, place, and remove surface barriers.

(5) Maintain sterilizer including, at a minimum, proper instrument loading and unloading, operation cycle, spore testing, and handling and disposal of sterilization chemicals.

(6) Apply work practice controls as they relate to the following classification of sharps: anesthetic needles or syringes, orthodontic wires, and broken glass.

(7) Apply infection control protocol for the following laboratory devices: impressions, bite registrations, and prosthetic appliances.

(8) Perform waterline maintenance, including use of water tests and purging of waterlines.

(g) Clinical instruction shall include two experiences in the following areas, with one used for a clinical examination:

(1) Apply hand cleansing products and perform hand cleansing techniques and protocols.

(2) Apply, remove, and dispose of patient treatment gloves, utility gloves, overgloves, protective eyewear, masks, and clinical attire.

(3) Apply the appropriate techniques and protocols for the preparation, sterilization, and storage of instruments including, at a minimum, application of personal protective equipment, precleaning, ultrasonic cleaning, rinsing, sterilization wrapping, internal or external process indicators, labeling, sterilization, drying, storage, and delivery to work area.

(4) Preclean and disinfect contaminated operatory surfaces and devices, and properly use, place, and remove surface barriers.

(5) Maintain sterilizer including, at a minimum, proper instrument loading and unloading, operation cycle, spore testing, and handling and disposal of sterilization chemicals.

(6) Apply work practice controls as they relate to the following classification of sharps: anesthetic needles or syringes, orthodontic wires, and broken glass.

(7) Apply infection control protocol for the following laboratory devices: impressions, bite registrations, and prosthetic appliances.

(8) Perform waterline maintenance, including use of water tests and purging of waterlines.(h) 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.

(h) 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 Infection Control Courses (New 10/10)" within ninety (90) days of the effective date of these regulations.

STATE OF CALIFORNIA
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DEPARTMENT OF CONSUMER AFFAIRS

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NOTICE OF COMPLIANCE WITH NEW REQUIREMENTS FOR ORTHODONTIC ASSISTANT PERMIT COURSE

To maintain approval by the Board, each Orthodontic Assistant Permit Course that was approved prior to the date that Sections 1070, 1070.1 and 1070.7 became effective must complete and submit this form to the Board at its offices no later than 90 days from the effective date of these new requirements. Any student graduating from such a course will not be accepted to sit for examination or qualify for registration until this form has been submitted to the Board. Certificates of Completion issued by educational course providers not meeting Notice submission requirements will not be recognized by the Board.

I, _____*Enter Name*),

Course Provider for _____*Enter Full Name of Educational Institution, Organization, or Course Provider*) **HEREBY CERTIFY:**

1) **I have read the attached regulations pertaining to the approval of Orthodontic Assistant Permit Courses, including Sections 1070, 1070.1 and 1070.7 of Title 16 of the California Code of Regulations;**

2) **I have the authority to sign this notice on behalf of the educational institution, organization, or course provider; and,**

3) **That to the best of my knowledge, information and belief, the institution, organization, or course provider and its programs or courses comply with these regulations and have been in compliance with these regulations since** _____(*Insert Date*).

I certify under penalty of perjury under the laws of the State of California that this Notice of Compliance is true and correct.

_____

Signature of Course Provider **DATE**

Printed Name of Course Provider: _____

Name of Educational Institution, Organization, or Course Provider:

_____

Address of Educational Institution, Organization, or Course Provider:

_____

Telephone Number: _____ **Email Address:** _____

NOTICE OF COLLECTION OF PERSONAL INFORMATION

Disclosure of your personal information is mandatory. The information on this application is required pursuant to Title 16, California Code of Regulations Sections 1070, 1070.7. Failure to provide any of the required information will result in the form being rejected as incomplete and your approval may be withdrawn for noncompliance. The information provided will be used to determine compliance with Article 2 of Division 10 of Title 16 of the California Code of Regulations (beginning at Section 1070). The information collected may be transferred to other governmental and enforcement agencies. Individuals have a right of access to records containing personal information pertaining to that individual that are maintained by the Board, unless the records are exempted from disclosure by Section 1798.40 of the Civil Code. Individuals may obtain information regarding the location of his or her records by contacting the Executive Officer at the Board at the address and telephone number listed above.

REGULATIONS PERTAINING TO THE APPROVAL OF ORTHODONTIC ASSISTANT PERMIT COURSES

Title 16 of the California Code of Regulations

Section 1070. General Provisions Governing All Dental Assistant Educational Programs and Courses.

(a) (1) The criteria in subdivisions (b) to (h), inclusive, shall be met by a dental assisting program or course and all orthodontic assisting and dental sedation assisting permit programs or courses to secure and maintain approval by the board as provided in this article.

(2) The board may approve, provisionally approve, or deny approval of any program or course for which an application to the Board for approval is required. All RDA and RDAEF programs and dental assisting educational courses shall be re-evaluated approximately every seven years, but may be subject to re-evaluation and inspection by the Board at any time to review and investigate compliance with this article and the Act. Re-evaluation may include a site visit or written documentation that ensures compliance with all regulations. Results of re-evaluation shall be reported to the Board or its designee for final consideration and continuance of program or course approval, provisional approval and denial of approval.

(3) Program and course records shall be subject to inspection by the board at any time.

(4) The board may withdraw approval at any time that it determines that a program or course does not meet the requirements of this article or any other requirement in the Act

(5) All programs and courses shall be established at the postsecondary educational level or deemed equivalent thereto by the board.

(6) The Board or its designee may approve, provisionally approve, or deny approval to any such program. Provisional approval shall not be granted for a period which exceeds beyond the length of the program. When the Board provisionally approves a program, it shall state the reasons therefore. Provisional approval shall be limited to those programs which substantially comply with all existing standards for full approval. A program given provisional approval shall immediately notify each student of such status. If the Board denies approval of a program, the specific reasons therefore shall be provided to the program by the Board in writing within 90 days after such action.

(b) The program or course director shall possess a valid, active, and current license issued by the board or the dental hygiene committee. The program or course director shall actively participate in and be responsible for the administration of the program or course. Specifically, the program or course director shall be responsible for the following requirements:

(1) Maintaining for a period of not less than five years copies of curricula, program outlines, objectives, and grading criteria, and copies of faculty credentials, licenses, and certifications, and individual student records, including those necessary to establish satisfactory completion of the program or course.

(2) Informing the board of any major change to the program or course content, physical facilities, or faculty, within 10 days of the change.

(3) Ensuring that all staff and faculty involved in clinical instruction meet the requirements set forth in this article.

(c) Course faculty and instructional staff shall be authorized to provide instruction by the program or course director and the educational facility in which instruction is provided.

(d) No faculty or instructional staff member shall instruct in any procedure that he or she does not hold a license or permit in California to perform. Each faculty or instructional staff member shall possess a valid, active, and current license issued by the Board of the Dental Hygiene Committee of California, shall have been licensed or permitted for a minimum of two years and possess experience in the subject matter he or she is teaching. An instructor who has held a license as a registered dental assistant or registered dental assistant in extended functions for at least two years, who then becomes a permit holder as an Orthodontic Assistant on or after January 1, 2010 shall not be required to have held such a permit for two years in order to instruct in the subject area.

(e) A certificate, diploma, or other evidence of completion shall be issued to each student who successfully completes the program or course and shall include the following: the student's name, the name of the program or course, the date of completion, and the signature of the program or course director or his or her designee.

(f) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties for which the program or course is approved to instruct.

(1) The location and number of general use equipment and armamentaria shall ensure that each student has the access necessary to develop minimum competency in all of the duties for which the program or course is approved to instruct. The program or course provider may either provide the specified equipment and supplies or require that the student provide them. Nothing in this section shall preclude a dental office that contains the equipment required by this section from serving as a location for laboratory instruction.

(2) Clinical instruction shall be of sufficient duration to allow the procedures to be performed to clinical proficiency. Operatories shall be sufficient in number to allow a ratio of at least one operatory for every five students who are simultaneously engaged in clinical instruction.

(A) Each operatory shall contain functional equipment, including a power-operated chair for patient or simulation-based instruction in a supine position, operator and assistant stools, air-water syringe, adjustable light, oral evacuation equipment, work surface, handpiece adaptation, and adjacent hand-washing sink

(B) Each operatory shall be of sufficient size to simultaneously accommodate one student, one instructor, and one patient or student partner.

(C) Prior to clinical assignments, students must demonstrate minimum competence in laboratory or preclinical performance of the procedures they will be expected to perform in their clinical experiences.

(g) The program or course shall establish written clinical and laboratory protocols that comply with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. The program or course shall provide these protocols to all students, faculty, and staff to ensure compliance. Adequate space shall be provided for handling, processing and sterilizing all armamentarium.

(h) A written policy on managing emergency situations shall be made available to all students, faculty, and instructional staff. All faculty and staff involved in the direct oversight of patient care activities shall be certified in basic life support procedures, including cardiopulmonary resuscitation. Recertification intervals may not exceed two years. The program or course director shall ensure and document compliance by faculty and instructional staff. A program or course shall sequence curriculum in such a manner so as to ensure that students complete instruction in basic life support prior to performing procedures on patients used for clinical instruction and evaluation.

(i) A detailed program or course outline shall clearly state, in writing, the curriculum subject matter, hours of didactic, laboratory, and clinical instruction, general program or course objectives, instructional objectives, theoretical content of each subject, and, where applicable, the use of practical application. Objective evaluation criteria shall be used for measuring student progress toward attainment of specific program or course objectives. Students shall be provided with all of the following:

(1) Specific performance objectives and the evaluation criteria used for measuring levels of competence for each component of a given procedure including those used for examinations.

(2) Standards of performance that state the minimum number of satisfactory performances that are required for each performance-evaluated procedure.

(3) Standards of performance for laboratory, preclinical, and clinical functions, those steps that would cause the student to fail the task being evaluated, a description of each of the grades that may be utilized during evaluation procedures, and a defined standard of performance.

(j) (1) As used in this article "extramural dental facility" means any clinical facility employed by an approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary campus of the approved program and in which dental treatment is rendered.

(2) If an extramural dental facility is utilized, students shall, as part of an extramural organized program of instruction, be provided with planned, supervised clinical instruction. Laboratory and preclinical instruction shall be performed under the direct supervision of program or course faculty or instructional staff and shall not be provided in an extramural dental facility.

(3) The program or course director, or a designated faculty member, shall be responsible for selecting extramural clinical sites and evaluating student competence before and after the clinical assignment.

(4) Prior to student assignment in an extramural dental facility, the program or course director, or a designated faculty or instructional staff member, shall orient dentists and all licensed dental healthcare workers who may provice instruction, evaluation and oversight of the student in the clinical setting. Orientation shall include, at a minimum, the objectives of the program or course, the student's preparation for the clinical assignment, and a review of procedures and criteria to be used by the dentist or the licensed personnel in the extramural dental facility in evaluating the student during the assignment, which shall be the same as the evaluation criteria used within the program or course.

(5) There shall be a written contract of affiliation between the program and each extramural dental facility that includes written affirmation of compliance with the regulations of this Article.

1070.7. Approval of Orthodontic Assistant Permit Courses

In addition to the requirements of Sections 1070 and 1070.1, the following criteria shall be met by a orthodontic assistant permit course to secure and maintain approval by the board.

(a) The course shall be of sufficient duration for the student to develop minimum competence in all of the duties that orthodontic assistant permitholders are authorized to perform, but in no event less than 84 hours, including at least 24 hours of didactic instruction, at least 28 hours of laboratory instruction, and at least 32 hours of clinical instruction. A registered dental assistant shall not be required to complete further instruction in the duties of placing ligature ties and archwires, removing orthodontic bands, and removing excess cement from tooth surfaces with a hand instrument. The course hours for a student who holds a valid and current registered dental assistant license shall be no less than 55 hours, including 11 didactic hours, 24 laboratory hours, and 20 clinical hours. A registered dental assistant who has completed a board-approved course in the use of an ultrasonic scaler shall not be required to complete further instruction in that duty. The course hours for a student who holds a valid and current registered dental assistant license and who has completed a Board-approved course in the use of an ultrasonic scaler shall be no less than 51 hours, including 9 didactic, 22 laboratory, and 20 clinical.

(b) The minimum requirements for equipment and armamentaria shall include banded or bonded orthodontic typodonts in the ratio of at least one for every four students, bench mount or dental chair mounted mannequin head, curing light, regular typodont with full dentition and soft gingiva in the ratio of at least one for every four students, a selection of orthodontic instruments and adjunct material for all of the procedures that orthodontic assistant permitholders are authorized to perform under Business and Professions Code Section 1750.3.

(c) In addition to the requirements of Section 1070, all faculty or instructional staff members responsible for clinical evaluation shall have completed a two-hour methodology course in clinical evaluation prior to conducting clinical evaluations of students.
(d) Areas of instruction shall include, at a minimum, the instruction specified in subdivisions (e) to (j), inclusive, as well as, instruction in basic background information on orthodontic practice."Basic background information on orthodontic practice" means, for purposes of this subdivision, the orthodontic treatment review, charting, patient education, and legal and infection control requirements as they apply to orthodontic practice.
(e) The following requirements shall be met for sizing, fitting, cementing, and removing orthodontic bands:
(1) Didactic instruction shall contain the following:
(A) Theory of band positioning and tooth movement.
(B) Characteristics of band material: malleability, stiffness, ductility, and work hardening.
(C) Techniques for orthodontic banding and removal, which shall include all of the following:
(i) Armamentaria.
(ii) General principles of fitting and removing bands.
(iii) Normal placement requirements of brackets, tubes, lingual sheaths, lingual cleats, and buttons onto bands.
(iv) Orthodontic cements and adhesive materials: classifications, armamentaria, and mixing technique.
(v) Cementing bands: armamentaria, mixing technique, and band cementation procedures.
(vi) Procedure for removal of bands after cementation.
(2) Laboratory instruction shall include typodont experience in the sizing, fitting, cementing, and removal of four posterior first molar bands a minimum of two times, with the cementing and removal of two first molar bands used as a practical examination.
(3) Clinical instruction shall include the sizing, fitting, cementing, and removal of four posterior first molar bands on at least two patients.
(f) The following requirements shall be met for preparing teeth for bonding:
(1) Didactic instruction shall contain the following:
(A) Chemistry of etching materials and tooth surface preparation
(B) Application and time factors
(C) Armamentaria
(D) Techniques for tooth etching.
(2) Laboratory instruction shall include typodont experience with etchant application in preparation for subsequent bracket bonding on four anterior and four posterior teeth a minimum of four times each, with one of each of the four times used for a practical examination.
(3) Clinical instruction shall include etchant application in preparation for bracket bonding on anterior and posterior teeth on at least two patients.
(g) The following requirements shall be met for bracket positioning, bond curing, and removal of orthodontic brackets.
(1) Didactic instruction shall include the following elements:
(A) Characteristics and methods of orthodontic bonding.
(B) Armamentaria.
(C) Types of bracket bonding surfaces.
(D) Bonding material characteristics, application techniques, and curing time factors.
(E) Procedure for direct and indirect bracket bonding.
(F) Procedures for bracket or tube removal.
(2) Laboratory instruction shall contain typodont experience with selecting, prepositioning, tooth etching, positioning, curing and removing of four anterior and four posterior brackets a minimum of four times each, with one each of the four times used for a practical examination.
(3) Clinical instruction shall contain selecting, adjusting, prepositioning, etching, curing and removal of anterior and posterior brackets on at least two patients.
(h) The following requirements shall be met for archwire placement and ligation:
(1) Didactic instruction shall contain the following:
(A) Archwire characteristics.
(B) Armamentaria.
(C) Procedures for placement of archwire previously adjusted by the dentist.
(D) Ligature systems, purpose and types, including elastic, wire, and self-ligating.
(2) Laboratory instruction shall contain typodont experience on the following:
(A) The insertion of a preformed maxillary and mandibular archwire a minimum of four times per arch, with one of each of the four times used for a practical examination.
(B) Ligation of maxillary and mandibular archwire using elastic or metal ligatures or self-ligating brackets a minimum of four times per arch, with one of each of the four times used for a practical examination.
(3) Clinical instruction shall contain the following:
(A) Insertion of a preformed maxillary and mandibular archwire on at least two patients.

(B) Ligating both preformed maxillary and mandibular archwires using a combination of elastic and metal ligatures or self-ligating brackets on at least two patients for each.

(i) The following requirements shall be met for cement removal with a hand instrument:

(1) Didactic instruction shall contain the following:

(A) Armamentaria

(B) Techniques of cement removal using hand instruments and related materials

(2) Laboratory instruction shall contain typodont experience on the removal of excess cement supragingivally from an orthodontically banded typodont using a hand instrument four times, with one of the four times used for a practical examination.

(3) Clinical instruction shall contain removal of excess cement supragingivally from orthodontic bands with a hand instrument on at least two patients.

(j) Instruction for cement removal with an ultrasonic scaler shall be in accordance with the California Code of Regulations, Title 16, Division 10, Chapter 3, Article 2, Section 1070.5 governing courses in the removal of excess cement from teeth under orthodontic treatment with an ultrasonic scaler.

(k) 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.

(l) 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 Orthodontic Assistant Permit Courses (New 10/10)" within ninety (90) days of the effective date of these regulations.

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DEPARTMENT OF CONSUMER AFFAIRS

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NOTICE OF COMPLIANCE WITH NEW REQUIREMENTS FOR DENTAL SEDATION ASSISTANT PERMIT COURSE

To maintain approval by the Board, each Dental Sedation Assistant Permit Course that was approved prior to the date that Sections 1070, 1070.1 and 1070.8 became effective must complete and submit this form to the Board at its offices no later than 90 days from the effective date of these new requirements. Any student graduating from such a course will not be accepted to sit for examination or qualify for registration until this form has been submitted to the Board. Certificates of Completion issued by educational course providers not meeting Notice submission requirements will not be recognized by the Board.

I, _____ *Enter Name*),

Course Provider for _____ *Enter Full Name of Educational Institution, Organization, or Course Provider*) **HEREBY CERTIFY:**

1) **I have read the attached regulations pertaining to the approval of Dental Sedation Assistant Permit Courses, including Sections 1070, 1070.1 and 1070.8 of Title 16 of the California Code of Regulations;**

2) **I have the authority to sign this notice on behalf of the educational institution, organization, or course provider; and,**

3) **That to the best of my knowledge, information and belief, the institution, organization, or course provider and its programs or courses comply with these regulations and have been in compliance with these regulations since** _____ (*Insert Date*).

I certify under penalty of perjury under the laws of the State of California that this Notice of Compliance is true and correct.

_____

Signature of Course Provider **DATE**

Printed Name of Course Provider: _____

Name of Educational Institution, Organization, or Course Provider:

_____

Address of Educational Institution, Organization, or Course Provider:

_____

Telephone Number: _____ **Email Address:** _____

NOTICE OF COLLECTION OF PERSONAL INFORMATION

Disclosure of your personal information is mandatory. The information on this application is required pursuant to Title 16, California Code of Regulations Sections 1070, 1070.8. Failure to provide any of the required information will result in the form being rejected as incomplete and your approval may be withdrawn for noncompliance. The information provided will be used to determine compliance with Article 2 of Division 10 of Title 16 of the California Code of Regulations (beginning at Section 1070). The information collected may be transferred to other governmental and enforcement agencies. Individuals have a right of access to records containing personal information pertaining to that individual that are maintained by the Board, unless the records are exempted from disclosure by Section 1798.40 of the Civil Code. Individuals may obtain information regarding the location of his or her records by contacting the Executive Officer at the Board at the address and telephone number listed above.

REGULATIONS PERTAINING TO THE APPROVAL OF DENTAL SEDATION ASSISTANT PERMIT COURSES

Title 16 of the California Code of Regulations

Section 1070. General Provisions Governing All Dental Assistant Educational Programs and Courses.

(a) (1) The criteria in subdivisions (b) to (h), inclusive, shall be met by a dental assisting program or course and all orthodontic assisting and dental sedation assisting permit programs or courses to secure and maintain approval by the board as provided in this article.

(2) The board may approve, provisionally approve, or deny approval of any program or course for which an application to the Board for approval is required. All RDA and RDAEF programs and dental assisting educational courses shall be re-evaluated approximately every seven years, but may be subject to re-evaluation and inspection by the Board at any time to review and investigate compliance with this article and the Act. Re-evaluation may include a site visit or written documentation that ensures compliance with all regulations. Results of re-evaluation shall be reported to the Board or its designee for final consideration and continuance of program or course approval, provisional approval and denial of approval.

(3) Program and course records shall be subject to inspection by the board at any time.

(4) The board may withdraw approval at any time that it determines that a program or course does not meet the requirements of this article or any other requirement in the Act

(5) All programs and courses shall be established at the postsecondary educational level or deemed equivalent thereto by the board.

(6) The Board or its designee may approve, provisionally approve, or deny approval to any such program. Provisional approval shall not be granted for a period which exceeds beyond the length of the program. When the Board provisionally approves a program, it shall state the reasons therefore. Provisional approval shall be limited to those programs which substantially comply with all existing standards for full approval. A program given provisional approval shall immediately notify each student of such status. If the Board denies approval of a program, the specific reasons therefore shall be provided to the program by the Board in writing within 90 days after such action.

(b) The program or course director shall possess a valid, active, and current license issued by the board or the dental hygiene committee. The program or course director shall actively participate in and be responsible for the administration of the program or course. Specifically, the program or course director shall be responsible for the following requirements:

(1) Maintaining for a period of not less than five years copies of curricula, program outlines, objectives, and grading criteria, and copies of faculty credentials, licenses, and certifications, and individual student records, including those necessary to establish satisfactory completion of the program or course.

(2) Informing the board of any major change to the program or course content, physical facilities, or faculty, within 10 days of the change.

(3) Ensuring that all staff and faculty involved in clinical instruction meet the requirements set forth in this article.

(c) Course faculty and instructional staff shall be authorized to provide instruction by the program or course director and the educational facility in which instruction is provided.

(d) No faculty or instructional staff member shall instruct in any procedure that he or she does not hold a license or permit in California to perform. Each faculty or instructional staff member shall possess a valid, active, and current license issued by the Board of the Dental Hygiene Committee of California, shall have been licensed or permitted for a minimum of two years and possess experience in the subject matter he or she is teaching. An instructor who has held a license as a registered dental assistant or registered dental assistant in extended functions for at least two years, who then becomes a permit holder as an Orthodontic Assistant on or after January 1, 2010 shall not be required to have held such a permit for two years in order to instruct in the subject area.

(e) A certificate, diploma, or other evidence of completion shall be issued to each student who successfully completes the program or course and shall include the following: the student's name, the name of the program or course, the date of completion, and the signature of the program or course director or his or her designee.

(f) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties for which the program or course is approved to instruct.

(1) The location and number of general use equipment and armamentaria shall ensure that each student has the access necessary to develop minimum competency in all of the duties for which the program or course is approved to instruct. The program or course provider may either provide the specified equipment and supplies or require that the student provide them. Nothing in this section shall preclude a dental office that contains the equipment required by this section from serving as a location for laboratory instruction.

(2) Clinical instruction shall be of sufficient duration to allow the procedures to be performed to clinical proficiency. Operatories shall be sufficient in number to allow a ratio of at least one operatory for every five students who are simultaneously engaged in clinical instruction.

(A) Each operatory shall contain functional equipment, including a power-operated chair for patient or simulation-based instruction in a supine position, operator and assistant stools, air-water syringe, adjustable light, oral evacuation equipment, work surface, handpiece adaptation, and adjacent hand-washing sink

(B) Each operatory shall be of sufficient size to simultaneously accommodate one student, one instructor, and one patient or student partner.

(C) Prior to clinical assignments, students must demonstrate minimum competence in laboratory or preclinical performance of the procedures they will be expected to perform in their clinical experiences.

(g) The program or course shall establish written clinical and laboratory protocols that comply with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. The program or course shall provide these protocols to all students, faculty, and staff to ensure compliance. Adequate space shall be provided for handling, processing and sterilizing all armamentarium.

(h) A written policy on managing emergency situations shall be made available to all students, faculty, and instructional staff. All faculty and staff involved in the direct oversight of patient care activities shall be certified in basic life support procedures, including cardiopulmonary resuscitation. Recertification intervals may not exceed two years. The program or course director shall ensure and document compliance by faculty and instructional staff. A program or course shall sequence curriculum in such a manner so as to ensure that students complete instruction in basic life support prior to performing procedures on patients used for clinical instruction and evaluation.

(i) A detailed program or course outline shall clearly state, in writing, the curriculum subject matter, hours of didactic, laboratory, and clinical instruction, general program or course objectives, instructional objectives, theoretical content of each subject, and, where applicable, the use of practical application. Objective evaluation criteria shall be used for measuring student progress toward attainment of specific program or course objectives. Students shall be provided with all of the following:

(1) Specific performance objectives and the evaluation criteria used for measuring levels of competence for each component of a given procedure including those used for examinations.

(2) Standards of performance that state the minimum number of satisfactory performances that are required for each performance-evaluated procedure.

(3) Standards of performance for laboratory, preclinical, and clinical functions, those steps that would cause the student to fail the task being evaluated, a description of each of the grades that may be utilized during evaluation procedures, and a defined standard of performance.

(j) (1) As used in this article "extramural dental facility" means any clinical facility employed by an approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary campus of the approved program and in which dental treatment is rendered.

(2) If an extramural dental facility is utilized, students shall, as part of an extramural organized program of instruction, be provided with planned, supervised clinical instruction. Laboratory and preclinical instruction shall be performed under the direct supervision of program or course faculty or instructional staff and shall not be provided in an extramural dental facility.

(3) The program or course director, or a designated faculty member, shall be responsible for selecting extramural clinical sites and evaluating student competence before and after the clinical assignment.

(4) Prior to student assignment in an extramural dental facility, the program or course director, or a designated faculty or instructional staff member, shall orient dentists and all licensed dental healthcare workers who may provice instruction, evaluation and oversight of the student in the clinical setting. Orientation shall include, at a minimum, the objectives of the program or course, the student's preparation for the clinical assignment, and a review of procedures and criteria to be used by the dentist or the licensed personnel in the extramural dental facility in evaluating the student during the assignment, which shall be the same as the evaluation criteria used within the program or course.

(5) There shall be a written contract of affiliation between the program and each extramural dental facility that includes written affirmation of compliance with the regulations of this Article.

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 section, the following definitions apply: "IV" means "intravenous", "AED" means automated external defibrillator, "CO2" means carbon dioxide, and ""ECG" or "EKG" means electrocardiogram.

(a)(1) In addition to the requirements of Section 1070, all faculty or instructional staff members responsible for clinical evaluation shall have completed a two-hour methodology course in clinical evaluation prior to conducting clinical evaluations of students.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 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 sedation or

general anesthesia, who shall be at the patient's chairside while conscious 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 (j), (k), (l), (m), and (n) of this Section during no less than twenty (20) supervised cases utilizing conscious 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 that the California Code of Regulations, Title 16, Division 10, Chapter 2, Article 5, Section 1043 require for the administration of general anesthesia or conscious 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.

(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.

(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 (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 sedation, deep sedation, and general anesthesia.

(7) Overview of patient monitoring during conscious 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 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 sedation, deep sedation, and general anesthesia.

(4) Review of respiratory and circulatory physiology and related anatomy, with special emphasis on establishing and maintaining a patent 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.

(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 but not be limited to, 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 or conscious 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 ECG/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 ECG/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 section.
(A) Assessment of blood pressure and pulse both manually and utilizing an automatic system.
(B) Placement and assessment of an electrocardiogram (ECG/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: The student shall demonstrate proficiency in each of the following tasks, under supervision of faculty or instructional staff as described in section 1070.8(a)(3), utilizing patients and shall then be eligible to complete an examination on this section.
(A) Assessment of blood pressure and pulse both manually and utilizing an automatic system.
(B) Placement and assessment of an electrocardiogram (ECG/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 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: 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), utilizing patients and shall then be eligible to complete an examination on this 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 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 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 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, ands shall 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 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)" within ninety (90) days of the effective date of these regulations.

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NOTICE OF COMPLIANCE WITH NEW REQUIREMENTS FOR REGISTERED DENTAL ASSISTANT IN EXTENDED FUNCTIONS EDUCATIONAL PROGRAMS

To maintain approval by the Board, each Registered Dental Assistant in Extended Functions (RDAEF) educational program that was approved prior to the date that Sections 1070, 1070.1 and 1071 became effective must complete and submit this form to the Board at its offices no later than 90 days from the effective date of these new requirements. Any student graduating from such a program will not be accepted to sit for examination or qualify for registration until this form has been submitted to the Board.

I, _____*Enter Name*),

Program Director for _____ *(Enter Full Name of Educational Institution or Program)* **HEREBY CERTIFY:**

1) **I have read the attached regulations pertaining to the approval of Registered Dental Assistant in Extended Functions (RDAEF) educational programs, including Sections 1070 and 1071 of Title 16 of the California Code of Regulations;**

2) **I have the authority to sign this notice on behalf of the educational institution or program; and,**

3) **That to the best of my knowledge, information and belief, the institution and its RDAEF programs or courses comply with these regulations and have been in compliance with these regulations since** _____*(Insert Date)*.

I certify under penalty of perjury under the laws of the State of California that this Notice of Compliance is true and correct.

_____

Signature of Program Director **DATE**

Printed Name of Program Director: _____

Name of Educational Institution or Program: _____

Address of Educational Institution or Program: _____

Telephone Number: _____ **Email Address:** _____

NOTICE OF COLLECTION OF PERSONAL INFORMATION

Disclosure of your personal information is mandatory. The information on this application is required pursuant to Title 16, California Code of Regulations Sections 1070, 1071. Failure to provide any of the required information will result in the form being rejected as incomplete and your approval may be withdrawn for noncompliance. The information provided will be used to determine compliance with Article 2 of Division 10 of Title 16 of the California Code of Regulations (beginning at Section 1070). The information collected may be transferred to other governmental and enforcement agencies. Individuals have a right of access to records containing personal information pertaining to that individual that are maintained by the Board, unless the records are exempted from disclosure by Section 1798.40 of the Civil Code. Individuals may obtain information regarding the location of his or her records by contacting the Executive Officer at the Board at the address and telephone number listed above.

REGULATIONS PERTAINING TO THE APPROVAL OF REGISTERED DENTAL ASSISTANT IN EXTENDED FUNCTIONS EDUCATIONAL PROGRAMS

Title 16 of the California Code of Regulations

Section 1070. General Provisions Governing All Dental Assistant Educational Programs and Courses.

(a) (1) The criteria in subdivisions (b) to (h), inclusive, shall be met by a dental assisting program or course and all orthodontic assisting and dental sedation assisting permit programs or courses to secure and maintain approval by the board as provided in this article.

(2) The board may approve, provisionally approve, or deny approval of any program or course for which an application to the Board for approval is required. All RDA and RDAEF programs and dental assisting educational courses shall be re-evaluated approximately every seven years, but may be subject to re-evaluation and inspection by the Board at any time to review and investigate compliance with this article and the Act. Re-evaluation may include a site visit or written documentation that ensures compliance with all regulations. Results of re-evaluation shall be reported to the Board or its designee for final consideration and continuance of program or course approval, provisional approval and denial of approval.

(3) Program and course records shall be subject to inspection by the board at any time.

(4) The board may withdraw approval at any time that it determines that a program or course does not meet the requirements of this article or any other requirement in the Act

(5) All programs and courses shall be established at the postsecondary educational level or deemed equivalent thereto by the board.

(6) The Board or its designee may approve, provisionally approve, or deny approval to any such program. Provisional approval shall not be granted for a period which exceeds beyond the length of the program. When the Board provisionally approves a program, it shall state the reasons therefore. Provisional approval shall be limited to those programs which substantially comply with all existing standards for full approval. A program given provisional approval shall immediately notify each student of such status. If the Board denies approval of a program, the specific reasons therefore shall be provided to the program by the Board in writing within 90 days after such action.

(b) The program or course director shall possess a valid, active, and current license issued by the board or the dental hygiene committee. The program or course director shall actively participate in and be responsible for the administration of the program or course. Specifically, the program or course director shall be responsible for the following requirements:

(1) Maintaining for a period of not less than five years copies of curricula, program outlines, objectives, and grading criteria, and copies of faculty credentials, licenses, and certifications, and individual student records, including those necessary to establish satisfactory completion of the program or course.

(2) Informing the board of any major change to the program or course content, physical facilities, or faculty, within 10 days of the change.

(3) Ensuring that all staff and faculty involved in clinical instruction meet the requirements set forth in this article.

(c) Course faculty and instructional staff shall be authorized to provide instruction by the program or course director and the educational facility in which instruction is provided.

(d) No faculty or instructional staff member shall instruct in any procedure that he or she does not hold a license or permit in California to perform. Each faculty or instructional staff member shall possess a valid, active, and current license issued by the Board of the Dental Hygiene Committee of California, shall have been licensed or permitted for a minimum of two years and possess experience in the subject matter he or she is teaching. An instructor who has held a license as a registered dental assistant or registered dental assistant in extended functions for at least two years, who then becomes a permit holder as an Orthodontic Assistant on or after January 1, 2010 shall not be required to have held such a permit for two years in order to instruct in the subject area.

(e) A certificate, diploma, or other evidence of completion shall be issued to each student who successfully completes the program or course and shall include the following: the student's name, the name of the program or course, the date of completion, and the signature of the program or course director or his or her designee.

(f) Facilities and class scheduling shall provide each student with sufficient opportunity, with instructor supervision, to develop minimum competency in all duties for which the program or course is approved to instruct.

(1) The location and number of general use equipment and armamentaria shall ensure that each student has the access necessary to develop minimum competency in all of the duties for which the program or course is approved to instruct. The program or course provider may either provide the specified equipment and supplies or require that the student provide them. Nothing in this section shall preclude a dental office that contains the equipment required by this section from serving as a location for laboratory instruction.

(2) Clinical instruction shall be of sufficient duration to allow the procedures to be performed to clinical proficiency. Operatories shall be sufficient in number to allow a ratio of at least one operatory for every five students who are simultaneously engaged in clinical instruction.

(A) Each operatory shall contain functional equipment, including a power-operated chair for patient or simulation-based instruction in a supine position, operator and assistant stools, air-water syringe, adjustable light, oral evacuation equipment, work surface, handpiece adaptation, and adjacent hand-washing sink

(B) Each operatory shall be of sufficient size to simultaneously accommodate one student, one instructor, and one patient or student partner.

(C) Prior to clinical assignments, students must demonstrate minimum competence in laboratory or preclinical performance of the procedures they will be expected to perform in their clinical experiences.

(g) The program or course shall establish written clinical and laboratory protocols that comply with the board's Minimum Standards for Infection Control California Code of Regulations Title 16, Division 10, Chapter 1, Article 1, Section 1005 and other federal, state, and local requirements governing infection control. The program or course shall provide these protocols to all students, faculty, and staff to ensure compliance. Adequate space shall be provided for handling, processing and sterilizing all armamentarium.

(h) A written policy on managing emergency situations shall be made available to all students, faculty, and instructional staff. All faculty and staff involved in the direct oversight of patient care activities shall be certified in basic life support procedures, including cardiopulmonary resuscitation. Recertification intervals may not exceed two years. The program or course director shall ensure and document compliance by faculty and instructional staff. A program or course shall sequence curriculum in such a manner so as to ensure that students complete instruction in basic life support prior to performing procedures on patients used for clinical instruction and evaluation.

(i) A detailed program or course outline shall clearly state, in writing, the curriculum subject matter, hours of didactic, laboratory, and clinical instruction, general program or course objectives, instructional objectives, theoretical content of each subject, and, where applicable, the use of practical application. Objective evaluation criteria shall be used for measuring student progress toward attainment of specific program or course objectives. Students shall be provided with all of the following:

(1) Specific performance objectives and the evaluation criteria used for measuring levels of competence for each component of a given procedure including those used for examinations.

(2) Standards of performance that state the minimum number of satisfactory performances that are required for each performance-evaluated procedure.

(3) Standards of performance for laboratory, preclinical, and clinical functions, those steps that would cause the student to fail the task being evaluated, a description of each of the grades that may be utilized during evaluation procedures, and a defined standard of performance.

(j) (1) As used in this article "extramural dental facility" means any clinical facility employed by an approved dental assisting educational program for instruction in dental assisting that exists outside or beyond the walls, boundaries or precincts of the primary campus of the approved program and in which dental treatment is rendered.

(2) If an extramural dental facility is utilized, students shall, as part of an extramural organized program of instruction, be provided with planned, supervised clinical instruction. Laboratory and preclinical instruction shall be performed under the direct supervision of program or course faculty or instructional staff and shall not be provided in an extramural dental facility.

(3) The program or course director, or a designated faculty member, shall be responsible for selecting extramural clinical sites and evaluating student competence before and after the clinical assignment.

(4) Prior to student assignment in an extramural dental facility, the program or course director, or a designated faculty or instructional staff member, shall orient dentists and all licensed dental healthcare workers who may provice instruction, evaluation and oversight of the student in the clinical setting. Orientation shall include, at a minimum, the objectives of the program or course, the student's preparation for the clinical assignment, and a review of procedures and criteria to be used by the dentist or the licensed personnel in the extramural dental facility in evaluating the student during the assignment, which shall be the same as the evaluation criteria used within the program or course.

(5) There shall be a written contract of affiliation between the program and each extramural dental facility that includes written affirmation of compliance with the regulations of this Article.

Section 1071. Approval of RDAEF Educational Programs.

(a) A new educational program for RDAEF's shall apply for and receive approval prior to operation. The Board may approve, provisionally approve, or deny approval of any such program. The Board may, in lieu of conducting its own investigation, accept the findings of any commission or accreditation agency approved by the Board and adopt those findings as its own.

(b) In addition to the requirements of Sections 1070 and 1070.1, the following criteria shall be met by an educational program for registered dental assistants in extended functions (RDAEF) to secure and maintain approval by the board.

(1) A program applying for approval to teach all of the duties specified in Section 1753.5 shall comply with all of the requirements of this section.

(2) A program applying for approval to teach RDAEFs licensed on or before January 1, 2010 the additional duties specified in Section 1753.6 shall comply with all of the requirements of this section, except as follows:

(A) The program shall be no less than 320 hours, including at least 76 hours of didactic instruction, at least 186 hours of laboratory instruction, and at least 58 hours of clinical instruction.

(B) Students shall not be required to complete instruction related to the placement of gingival retraction cord, the taking of final impressions for permanent indirect restorations, or the fitting of endodontic master points and accessory points.

(c) In order to be admitted to the program, each student shall possess a valid, active, and current license as a registered dental assistant issued by the board and shall submit documentary evidence of successful completion of a board-approved pit and fissure sealant course.

(d) In addition to the requirements of Sections 1070 and 1070.1, all faculty members responsible for clinical evaluation shall have completed a course or certification program in educational methodology of at least six (6) hours by January 1, 2012, unless he or she holds any one of the following: a postgraduate degree in education, a Ryan Designated Subjects Vocational Education Teaching Credential, a Standard Designated Subjects Teaching Credential, or, a Community College Teaching Credential. Each faculty member employed on or after January 1, 2012, shall complete a course or certification program in educational methodology within six months of employment. The program director or designated administrator shall be responsible to obtain and maintain records of each faculty member showing evidence of having met this regulation.
(e) The program shall be of sufficient duration for the student to develop minimum competence in all of the duties that RDAEFs are authorized to perform, but in no event less than 412 hours, including at least 100 hours of didactic instruction, at least 206 hours of laboratory instruction, and at least 106 hours of clinical instruction. All laboratory and simulated clinical instruction shall be provided under the direct supervision of program staff. Clinical instruction shall be provided under the direct supervision of a licensed dentist and may be completed in an extramural dental facility as defined in Section 1070.1(i).
(f) The following requirements are in addition to the requirements of Sections 1070 and 1070.1:

(1) The following are minimum requirements for equipment and armamentaria:

(A) Laboratory facilities with individual seating stations for each student and equipped with air, gas and air, or electric driven rotary instrumentation capability. Each station or operatory shall allow an articulated typodont to be mounted in a simulated head position.

(B) Clinical simulation facilities that provide simulated patient heads mounted in appropriate position and accommodating an articulated typodont in an enclosed intraoral environment, or mounted on a dental chair in a dental operatory. Clinical simulation spaces shall be sufficient to permit one simulation space for each two students at any one time.

(C) Articulated typodonts of both deciduous and permanent dentitions with flexible gingival tissues and with prepared teeth for each procedure to be performed in the laboratory and clinical simulation settings. One of each type of typodont is required for each student.

(D) A selection of restorative instruments and adjunct materials for all procedures that RDAEFs are authorized to perform.

(2) Notwithstanding Section 1070, there shall be at least one operatory for every two students who are simultaneously engaged in clinical instruction.

(g) Areas of instruction shall include, at a minimum, the instruction specified in subdivisions (g) to (m), inclusive, and the following didactic instruction:

(1) The following instruction as it relates to each of the procedures that RDAEFs are authorized to perform: restorative and prosthetic treatment review; charting; patient education; legal requirements; indications and contraindications; problem solving techniques; laboratory, preclinical, and clinical criteria and evaluation; and infection control protocol implementation.

(2) Dental science, including dental and oral anatomy, histology, oral pathology, normal or abnormal anatomical and physiological tooth descriptions, tooth morphology, basic microbiology relating to infection control, and occlusion.

(3) Characteristics and manipulation of dental materials related to each procedure.

(4) Armamentaria for all procedures.

(5) Principles, techniques, criteria, and evaluation for performing each procedure, including implementation of infection control protocols.

(6) Occlusion: the review of articulation of maxillary and mandibular arches in maximum intercuspation.

(7) Tooth isolation and matrix methodology review.

(h) General laboratory instruction shall include:

(1) Rubber dam application for tooth isolation in both maxillary and mandibular arches and for deciduous and permanent dentitions. A minimum of four experiences per arch is required, with two anterior and two posterior applications, with one of the applications used for a practical examination.

(2) Matrix placement for amalgam, and nonmetallic restorative material restorations in both primary and permanent dentitions, with three experiences for each cavity classification and for each material.

(3) Base, liner, and etchant placement on three posterior teeth for each base, liner, or etchant, with one of the three teeth used for a practical examination.

(i) With respect to preliminary evaluation of the patient's oral health, including, charting of existing conditions excluding periodontal assessment, intraoral and extraoral evaluation of soft tissue, classifying occlusion, and myofunctional evaluation:

(1) Didactic instruction shall contain the following:

(A) Normal anatomical structures: oral cavity proper, vestibule, and lips.

(B) Deviations from normal to hard tissue abnormalities to soft tissue abnormalities.

(C) Overview of classifications of occlusion and myofunction.

(D) Sequence of oral inspection: armamentaria, general patient assessment, review of medical history form, review of dental history form, oral cavity mouth-mirror inspection, and charting existing conditions.

(2) Preclinical instruction shall include performing an oral inspection on at least two other students.

(3) Clinical instruction shall include performing an oral inspection on at least two patients, with one of the two patients used for a clinical examination.

(j) With respect to sizing, fitting, and cementing endodontic master points and accessory points:

(1) Didactic instruction shall include the following:

(A) Review of objectives, canal preparation, filling of root canal space, including the role of the RDAEF as preparatory to condensation which is to be performed by the licensed dentist.
(B) Description and goals of filling technique using lateral condensation techniques.
(C) Principles and techniques of fitting and cementing master points and accessory points using lateral condensation including, characteristics, manipulation, use of gutta percha and related materials, and criteria for an acceptable master and accessory points technique using lateral condensation.

(2) Laboratory instruction shall include fitting and cementing master points and accessory points on extracted teeth or simulated teeth with canals in preparation for lateral condensation by the dentist, with at a minimum two experiences each on a posterior and anterior tooth. This instruction shall not include obturator based techniques or other techniques that employ condensation.

(3) Simulated clinical instruction shall include fitting and cementing master points and accessory points in preparation for condensation by the dentist with extracted or simulated teeth prepared for lateral condensation mounted in simulated patient heads mounted in appropriate position and accommodating and articulated typodont in an enclosed intraoral environment, or mounted on a dental chair in a dental operatory. This instruction shall not include obturator based techniques that employ condensation. Simulated clinical instruction shall include fitting and cementing master points and accessory points for lateral condensation by the dentist in at least four teeth, one of which shall be used for a practical exam.

(k) With respect to gingival retraction, general instruction shall include:

(1) Review of characteristics of tissue management as it relates to gingival retraction with cord and electrosurgery.

(2) Description and goals of cord retraction.

(3) Principles of cord retraction, including characteristics and manipulation of epinephrine, chemical salts classification of cord, characteristics of single versus double cord technique, and techniques and criteria for an acceptable cord retraction technique.

(l) With respect to final impressions for permanent indirect and toothborne restorations:

(1) Didactic instruction shall contain the following:

(A) Review of characteristics of impression material and custom.
(B) Description and goals of impression taking for permanent indirect restorations and toothborne prosthesis.
(C) Principles, techniques, criteria, and evaluation of impression taking for permanent indirect restorations and toothborne prosthesis.

(2) Laboratory instruction shall include the following:

(A) Cord retraction and final impressions for permanent indirect restorations, including impression taking of prepared teeth in maxillary and mandibular arches, one time per arch with elastomeric impression materials.
(B) Impressions for toothborne removable prostheses, including, at a minimum, taking a total of four impressions on maxillary and mandibular arches with simulated edentulous sites and rest preparations on at least two supporting teeth in each arch.

(3) Clinical instruction shall include taking final impressions on five cord retraction patients, with one used for a clinical examination.

(m) With respect to placing, contouring, finishing, and adjusting direct restorations:

(1) Didactic instruction shall contain the following:

(A) Review of cavity preparation factors and restorative material.
(B) Review of cavity liner, sedative, and insulating bases.
(C) Characteristics and manipulation of direct filling materials.
(D) Amalgam restoration placement, carving, adjusting and finishing, which includes principles, techniques, criteria and evaluation, and description and goals of amalgam placement, adjusting and finishing in children and adults.
(E) Glass-ionomer restoration placement, carving, adjusting, contouring and finishing, which includes, principles, techniques, criteria and evaluation, and description and goals of glass-ionomer placement and contouring in children and adults.
(F) Composite restoration placement, carving, adjusting, contouring and finishing in all cavity classifications, which includes, principles, techniques, criteria, and evaluation.

(2) Laboratory instruction shall include typodont experience on the following:

(A) Placement of Class I, II, and V amalgam restorations in eight prepared permanent teeth for each classification, and in four deciduous teeth for each classification.
(B) Placement of Class I, II, III, and V composite resin restorations in eight prepared permanent teeth for each classification, and in four deciduous teeth for each classification.
(C) Placement of Class I, II, III, and V glass-ionomer restorations in four prepared permanent teeth for each classification, and in four deciduous teeth for each classification.

(3) Simulated clinical instruction shall include experience with typodonts mounted in simulated heads on a dental chair or in a simulation laboratory as follows:

(A) Placement of Class I, II, and V amalgam restorations in four prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(B) Placement of Class I, II, III, and V composite resin restorations in four prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(C) Placement of Class I, II, III, and V glass-ionomer restorations in four prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(4) Clinical instruction shall require proficient completion of placing, contouring and finishing at least twenty (20) direct restorations in prepared permanent teeth with the following requirements:

(A) At least fifty (50) percent of the experiences shall be Class II restorations using esthetic materials.

(B) At least twenty (20) percent of the experiences shall be Class V restorations using esthetic materials.

(C) At least ten (10) percent of the experiences shall use amalgam.

(D) Students who complete the 20 restorations and meet all the instructional requirements of this section may complete additional Class I,II,III or V restorations as deemed appropriate for program success.

(n) With respect to polishing and contouring existing amalgam restorations:

(1) Didactic instruction shall include principles, techniques, criteria and evaluation, and description and goals of amalgam polishing and contouring in children and adults.

(2) Laboratory instruction shall include typodont experience on polishing and contouring of Class I, II, and V amalgam restorations in three prepared permanent teeth for each classification, and in two deciduous teeth for each classification.

(3) Simulated clinical instruction shall include experience with typodonts mounted in simulated heads on a dental chair or in a simulation laboratory in the polishing and contouring of Class I, II, and V amalgam restorations in two prepared permanent teeth for each classification, with one of each classification used for a clinical examination.

(o) With respect to adjusting and cementing permanent indirect restorations:

(1) Didactic instruction shall contain the following:

(A) Review of fixed prosthodontics related to classification and materials for permanent indirect restorations, general crown preparation for permanent indirect restorations, and laboratory fabrication of permanent indirect restorations.

(B) Interocclusal registrations for fixed prosthesis, including principles, techniques, criteria, and evaluation.

(C) Permanent indirect restoration placement, adjustment, and cementation, including principles, techniques, criteria, and evaluation.

(2) Laboratory instruction shall include:

(A) Interocclusal registrations using elastomeric and resin materials. Two experiences with each material are required.

(B) Fitting, adjustment, and cementation of permanent indirect restorations on one anterior and one posterior tooth for each of the following materials, with one of each type used for a practical examination: ceramic, ceramometal, and cast metallic.

(3) Clinical experience for interocclusal registrations shall be performed on four patients who are concurrently having final impressions recorded for permanent indirect restorations, with one experience used for a clinical examination.

(4) Clinical instruction shall include fitting, adjustment, and cementation of permanent indirect restorations on at least two teeth.

(p) 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.

(q) 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 Registered Dental Assistant in Extended Functions Educational Programs (New 10/10)" within ninety (90) days of the effective date of these regulations.

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
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MEMORANDUM

DATE	November 4, 2010
TO	Dental Board Members
FROM	Donna Kantner, Manager, Licensing and Examination Unit
SUBJECT	**Agenda Item 6: Request by the California Dental Association Relating to Review and Possible Amendments to Title 16, California Code of Regulations (CCR) Section 1049 Relative to Mobile Dental Clinics**

The California Dental Association (CDA) submitted a letter on May 28, 2010, regarding the Board's current regulations relative to Mobile Dental Clinics and a request that this item be placed on the agenda of a Dental Board meeting.

Following is a copy of the letter and the current statutes and regulations that govern Mobile Dental Clinic permits.

May 28, 2010

Richard DeCuir, Executive Officer
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: Promulgating regulations governing mobile/portable dental providers

Dear Mr. DeCuir:

The California Dental Association has reviewed California's regulations governing mobile and portable dental providers and found the current regulations lacking appropriate measures to ensure accountability and public safety. We believe the Dental Board has the authority to promulgate additional regulations pursuant to Business and Professions Code sections 1601.3 and 1657.

The issues of concern and provisions we suggest are as follows:

1. Individuals receiving dental services receive culturally and linguistically appropriate, written information about the treatment they received including:
    a. Names and license numbers of all providers
    b. Services performed
    c. A description of any dental needs observed during a screening, assessment, or other form of visual inspection, or diagnosed during an exam
    d. Future appointment dates and times
    e. Contact information of the provider if an individual was referred to another provider
    f. Contact information for the mobile provider (phone number and address)
    g. Instructions for dental emergencies - who to contact and a phone number

It is important that individuals receive the above information because mobile dental providers are unlike community-based dentists in that their window of availability is far less. Mobile providers are essentially only available when they are treating patients and they are only available to the individuals at that particular site. After a set amount of time, they move to a different location. In the event of a dental emergency, this information will be needed to ensure individuals get the care they need. Additionally, knowing who provided care will allow another dentist to request records should that be necessary.

2. The mobile/portable provider has an official place of business in California, that is not a post office box, where official records are stored.

This information is imperative for records sharing and also for the purposes of serving legal documents.

3. The mobile/portable provider has a phone line for patients, dentists, or other interested parties to contact the mobile provider with emergencies, questions, requests for records, etc.
4. A written procedure for emergency follow-up care for patients treated by the mobile dental provider and that such procedures include arrangements for treatment in a dental facility permanently established in the area.
5. The mobile/portable provider submits proof to the dental board, via a letter, of a current working relationship with a community-based provider willing to accept patients for follow-up and emergency services.

Working collaboratively in a community is essential to ensure continuity of care. Mobile providers are not permanently established and therefore must rely on community-based providers to ensure their patients of record have access to care when the mobile provider is unavailable.

6. Language inclusive of current (RDHAP) and future dental professionals practicing within their scope. This language is needed to align the regulations with current scope of practices and to prevent the need to amend regulations if/when a new type of provider is approved by the state.
7. Exemption from these regulations for mobile/portable facilities operated or sponsored by the federal, state or local government.

The measures outlined above are for public protection and safety. The population served by the majority of mobile/portable dental providers is primarily located in underserved areas and these patients frequently speak English as a second language and may not understand how to advocate for themselves or know how to navigate the system to file a complaint should that become necessary.

We respectfully request this issue be placed on the agenda for a future Dental Board meeting. A thorough review of all sections of the Business and Professions Code, Health and Safety Code, and the California Code of Regulations Section 1049 pertaining to mobile and portable dental providers needs to be conducted to ensure accountability and public safety.

Sincerely,

Dean Chalios,
Vice President, Public Policy
California Dental Association

cc: Kristy Scheildge

Statutes

1601.3. (a) All committees of the board have the authority to evaluate all suggestions or requests for regulatory changes related to their committee. Committees shall have the authority to hold informational hearings in order to report and make appropriate recommendations to the board, after consultation with departmental legal counsel and the board's chief executive officer. The committees shall include in any report regarding a proposed regulatory change, at a minimum, the specific language or the proposed change or changes and the reasons therefor and any facts supporting the need for the change.

(b) No part of this section shall restrict the Dental Hygiene Committee of California from adopting, amending, or revoking regulations authorized by Article 9 (commencing with Section 1900).

1657. (a) A licensed dentist may operate one mobile dental clinic or unit registered as a dental office or facility. The mobile dental clinic or unit shall be registered and operated in accordance with regulations established by the board, provided these regulations are not designed to prevent or lessen competition in service areas. A mobile dental clinic or unit registered and operated in accordance with the board's regulations and that has paid the fees established by the board, including a mobile dental unit registered for the purpose specified in subdivision (d), shall otherwise be exempted from this article and Article 3.5 (commencing with Section 1658).

(b) A mobile service unit, as defined in subdivision (b) of Section 1765.105 of the Health and Safety Code, and a mobile unit operated by an entity that is exempt from licensure pursuant to subdivision (b), (c), or (h) of Section 1206 of the Health and Safety Code, are exempt from this article and Article 3.5 (commencing with Section 1658). Notwithstanding this exemption, the owner or operator of the mobile unit shall notify the board within 60 days of the date on which dental services are first delivered in the mobile unit, or the date on which the mobile unit's application pursuant to Section 1765.130 of the Health and Safety Code is approved, whichever is earlier.

(c) A licensee practicing in a mobile unit described in subdivision (b) is not subject to subdivision (a) as to that mobile unit.

(d) Notwithstanding Section 1625, a licensed dentist shall be permitted to operate a mobile dental unit provided by his or her property and casualty insurer as a temporary substitute site for the practice registered by him or her pursuant to Section 1650 as long as both of the following apply:

(1) The licensed dentist's registered place of practice has been rendered and remains unusable due to loss or calamity.

(2) The licensee's insurer registers the unit with the board in compliance with subdivision (a).

REGULATIONS

Section 1026. Mobile Dental Clinics.

(a) It is the intent of this section to provide a procedure whereby mobile dental clinics may be identified, qualified and approved by the board as an adjunct to, and an extension of, the clinical and laboratory departments of an approved dental school.

(b) As used in this article "mobile dental clinic" means and includes any clinical facility employed by an approved dental school for instruction in dentistry which may be moved, towed or transported from one location to another, and in which dental services are rendered.

(c) Dental services provided to the public by dental students in a mobile dental clinic shall constitute a part of the dental education program. The program shall be balanced in the sense that it will provide a potential for innovative teaching possibilities as well as providing a resource whereby the dental student may experience a greater exposure to aspects of dental practice than those aspects encountered in the primary clinical and laboratory environment of the dental school.

(d) Approved dental schools shall register mobile dental clinics with the board. Such registration shall be accompanied by information supplied by the dental school pertaining to faculty supervision, scope of treatment to be rendered, postoperative care, proposed itinerary showing locations by dates, discipline of which such instruction is a part, and a brief description of the equipment and facilities available. Any change in the foregoing information initially provided to the board shall be communicated to the board.

(e) Mobile dental clinics shall constitute a part of an approved dental school teaching program.

(f) The processing times for registration of a mobile dental clinic are set forth in Section 1061.

Section 1049. Mobile Dental Clinics.

(a) Definition. For purposes of Section 1657 of the code, a "mobile dental clinic" or "mobile dental unit" means any self-contained facility in which dentistry will be practiced which may be moved, towed, or transported from one location to another.

(b) Application for Permit. A licensed dentist who wishes to operate a mobile dental clinic shall apply to the board for a permit by providing evidence of compliance with the requirements of this section and paying the fee prescribed in Section 1021 for application for an additional office permit. The board shall inform an applicant for a permit in writing within 7 days whether the application is complete and accepted for filing or is deficient and what specific information is required. The board shall decide within 60 days after the filing of a completed application whether the applicant meets the requirements of a permit.

(c) Requirements.

(1) The applicant shall certify that:

(A) There is a written procedure for emergency follow-up care for patients treated in the mobile dental clinic and that such procedure includes arrangements for treatment in a dental facility which is permanently established in the area.

(B) The mobile dental clinic has communication facilities which will enable the operator thereof to contact necessary parties in the event of a medical or dental emergency.

(C) The mobile dental clinic conforms to all applicable federal, state and local laws, regulations and ordinances dealing with radiographic equipment, flammability, construction, sanitation and zoning and the applicant possesses all applicable county and city licenses or permits to operate the unit.

(D) The driver of the unit possesses a valid California driver's license.

(2) The applicant shall maintain an official business or mailing address of record which shall be filed with the board. The board shall be notified within 30 days of any change in the address of record. All written or printed documents available from or issued by the mobile dental clinic shall contain the official address of record for the mobile dental clinic.

(3) Each mobile dental clinic shall:

(A) Have ready access to a ramp or lift if services are provided to disabled persons.

(B) Have a properly functioning sterilization system.

(C) Have ready access to an adequate supply of potable water, including hot water.

(D) Have ready access to toilet facilities.

(E) Have a covered galvanized, stainless steel, or other noncorrosive metal container for deposit of refuse and waste materials.

(d) Transferability. A permit to operate a mobile dental clinic is not transferable.

(e) Renewal. A permit to operate a mobile dental clinic expires at the same time as the permit holder's dental license. The permit holder may apply for renewal and shall pay the fee set for renewal of an additional office permit.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
DENTAL BOARD OF CALIFORNIA
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MEMORANDUM

DATE	November 4, 2010
TO	Dental Board Members Dental Board of California
FROM	Karen Fischer, Administrative Analyst Dental Board of California
SUBJECT	**Agenda Item 7:** Future Meeting Dates for Board Meetings

The Dental Board will need to set the 2011 meeting schedule in order for staff to negotiate contracts for future meeting space locations. A 2011 calendar is attached for your reference.

Pursuant to Business and Professions Code, Section 1607, the Board shall meet regularly once each year in San Francisco and Los Angeles and at such other times and places as the Board may designate, for the purpose of transacting its business.

Following are possible dates in 2011 to consider:

Feb 10-11 or Feb 24-25
Mar 10-11
May 12-13 (in conjunction with CDA) or May 19-20
Aug 11-12 or Aug 18-19 or Aug 25-26
Nov 3-4

State Pay Period Calendar for 2011

JANUARY 2011
21 Days 168 Hours

SU	M	TU	W	TH	F	SA
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

FEBRUARY 2011
21 Days 168 Hours

SU	M	TU	W	TH	F	SA
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	1				

MARCH 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
			2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

APRIL 2011
21 Days 168 Hours

SU	M	TU	W	TH	F	SA
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

MAY 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

JUNE 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

JULY 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31	1					

AUGUST 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
		2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

SEPTEMBER 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

OCTOBER 2011
21 Days 168 Hours

SU	M	TU	W	TH	F	SA
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

NOVEMBER 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

DECEMBER 2011
22 Days 176 Hours

SU	M	TU	W	TH	F	SA
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

NOTE: Holidays and observed dates after July 1, 2009, are subject to any collective bargaining agreements negotiated in Fiscal Year 2009–2010 or thereafter.