DENTAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

PROPOSED REGULATORY LANGUAGE

Proposed amendments to the regulatory language are shown in single underline for new text and single ~~strikethrough~~ for deleted text.

Where the Board proposes to re-number existing paragraphs to a new paragraph within this section, the Board has ~~struck through~~ the existing number of the paragraph and underlined the new proposed paragraph number to show the proposed re-ordering of paragraphs within this section.

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

§ 1005. Minimum Standards for Infection Control.

(a) Definitions of terms used in this section:

(1) "Standard precautions" are ~~a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status,~~ infection prevention protocols and procedures established for use in any setting in which dental healthcare is delivered. These include: hand hygiene protocols and hand care, ~~use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure,~~ use of personal protective equipment, procedures for patient care items, ~~and~~ safe handling of sharps~~.~~, safe handling and disposal of contaminated medical waste, respiratory hygiene or cough etiquette, and use of disinfectant agents in accordance with this section. Standard precautions shall be used for care of all patients regardless of ~~their diagnoses or personal infectious status.~~ the procedure performed or the health history of the patient.

(4) "Instrument/device classifications" are categories used to identify patient care items ("items") as critical, semi-critical, or non-critical depending on the potential risk for infection associated with their intended use and their required level of sterilization or disinfection for safe practice, as follows:

~~(2)~~(A) "Critical items" ~~confer a high risk for infection if they are contaminated with any microorganism.~~ carry the highest risk of transmitting infection. These include all instruments, devices, and other items used to penetrate soft tissue or bone~~.~~, such as surgical instruments, periodontal instruments, hygiene scalers, and burs.

~~(3)~~ (B) “Semi-critical items” are instruments, devices, and other items that ~~are not used to penetrate soft tissue or bone, but contact oral mucous membranes, non-intact skin or other potentially infectious materials (OPIM).~~ come into contact with oral tissue, blood, or OPIM without penetration, such as those items used for intraoral examination, and dental procedures including dental mouth mirrors, amalgam condensers, reusable dental impression trays, and orthodontic pliers with plastic parts.

~~(4)~~ (C) “Non-critical items” are instruments, devices, equipment, and surfaces (“clinical contact surfaces”) that come in contact with soil (e.g., organic and inorganic material), debris, blood, OPIM and intact skin, but not oral mucous membranes, and are utilized extraorally or are indirectly contaminated with debris, blood, or OPIM during clinical procedures, such as dental X-ray machines, assistant cart attachments, dental material delivery systems, patient safety eyewear, plastic dental syringes, and countertops.

(5) “Disinfect” or “disinfection” means the use of a chemical solution to reduce or lower the number of microorganisms on inanimate objects using a Cal/EPA-registered product.

(6) “Disinfection classifications” are categories used to determine the effectiveness of a disinfectant agent to inactivate mycobacterium during surface disinfection procedures and are as follows:

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

~~(6)~~ (B) “Intermediate-level disinfection” ~~kills~~inactivates mycobacterium tuberculosis var bovis indicating that many human pathogens are also ~~killed~~inactivated. This process does not necessarily ~~kill~~inactivate spores.

~~(7)~~ (C) “High-level disinfection” ~~kills some, but not necessarily all bacterial spores. This process kills mycobacterium tuberculosis var bovis, bacteria, fungi, and viruses.~~ inactivates all vegetative bacteria, mycobacterium, viruses, fungi, and some bacterial spores.

(7) “Cal/EPA-registered” means a product registered by the U.S. Environmental Protection Agency (EPA) and the California Department of Pesticide Regulation for sale and use in California as a pesticide.

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

~~(9)~~(8) "Sterilization" is a validated process used to ~~render a product free of all forms of viable microorganisms.~~ eliminate all forms of microbial life using acceptable methods of sterilization set forth in this section.

~~(10)~~(9) "Cleaning" is the removal of visible soil ~~(e.g., organic and inorganic material),~~ debris, blood, and OPIM from objects and surfaces and shall be accomplished manually or mechanically using water with detergents or enzymatic products~~.~~ prior to the use of a sterilization device or disinfectant for surface disinfection, using one of the following applicable methods:

(A) Cleaning of clinical contact surfaces and non-critical items means scrubbing using water and a detergent, or a surface disinfectant, either of which is registered with Cal/EPA as a disinfectant to clean surfaces or items according to manufacturer's instructions.

(B) Cleaning of semi-critical or critical items means scrubbing with a long-handled brush or using an FDA-approved mechanical device to remove visible soil from contaminated items using detergents or enzymatic products. Acceptable mechanical cleaning devices shall include ultrasonic cleaners using enzymatic products or detergents that require manual drying, or devices manufactured specifically for washing and mechanical drying of dental instruments, cassettes, and devices prior to preparing for sterilization. All mechanical cleaning devices shall be used in accordance with the manufacturer's instructions for the device or item type and quantity being cleaned.

~~(11)~~(2) "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, OPIM~~other potentially infectious materials, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants, and shirts, are not considered to be PPE.

~~(12)~~(3) "Other Potentially Infectious Materials" (OPIM) means any ~~one~~ of the following:

(A) Human 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) Any unfixed tissue or organ (other than intact skin) from a human (living or dead).

(C) Any of the following, if known or reasonably likely to contain or be infected with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV):

1. Cell, tissue, or organ cultures from humans or experimental animals;

2. Blood, organs, or other tissues from experimental animals; or

3. Culture medium or other solutions.

~~(13)~~(10) "Dental Healthcare Personnel" (DHCP)~~,~~ are all paid and non-paid personnel in the ~~dental healthcare setting~~ treatment facility who might be occupationally exposed to infectious materials, including ~~body substances~~blood and OPIM, 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).

(11) "Contaminated medical waste" shall include "medical waste" as defined in Section 117690 of the Health and Safety Code occurring in the dental healthcare setting and shall not include those applicable items set forth in Section 117700 of the Health and Safety Code.

(b) All DHCP shall comply with all applicable infection control standard precautions and enforce the following applicable minimum standard precautions in the treatment facility to protect patients and DHCP and to minimize the transmission of pathogens in health care settings as mandated by the California Division of Occupational Safety and Health (Cal/OSHA).

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

(2) A written ~~protocol shall be developed, 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.~~ infection control plan detailing the protocols and procedures that shall be developed, maintained, and periodically updated for all standard precautions in accordance with the requirements of this section. The written infection control plan shall be made readily available to all DHCP at the treatment facility and reviewed and updated at least annually by the DHCP employer or employer-designated representative

responsible for infection control compliance, and as needed to maintain compliance with this section.

(3) A copy of this regulation shall be conspicuously posted in each ~~dental office.~~ treatment facility and included in the written infection control plan described in paragraph (2).

(4) Personal Protective Equipment~~:~~ (PPE):

~~(4)~~(A) All DHCP shall wear single-use, disposable surgical facemasks in combination with either chin length plastic face shields or protective eyewear during patient treatment or whenever there is potential for aerosol spray, splashing, or spattering of the following: droplet nuclei, blood, chemical or ~~germicidal~~disinfectant agents, or OPIM. For purposes of this section, "protective eyewear" includes safety glasses with side shields bearing evidence of compliance with American National Standard for Occupational and Education Personal Eye and Face Protection Devices ANSI/ISEA Z87.1-2020 (the "Z87" marking).

(B) A new, single-use, disposable surgical facemask shall be used for each patient at the beginning of their treatment session. Surgical facemask replacement shall occur at any point during a procedure where the mask becomes moist or soiled. ~~Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals.~~ After each patient treatment, surgical facemasks shall be changed and disposed when leaving laboratories or areas of patient care activities.

(C) Chin-length face shields and face visors are acceptable replacements for protective eyewear when worn in combination with a surgical facemask. Face shields and face visors shall not be used as a replacement for a surgical facemask. After each patient treatment, face shields and protective eyewear shall be cleaned, disinfected, or disposed when leaving laboratories or areas of patient care activities.

(D) Chemical and puncture-resistant utility gloves and chemical-resistant PPE shall be worn when handling hazardous chemicals and shall be worn in accordance with paragraph (6).

(E) Reusable protective eyewear, face shields, and visors shall be washed with soap and water, or if visibly soiled, cleaned and disinfected between patients.

~~(5)~~(F) Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of ~~germicides~~ disinfectants or when handling contaminated items. All DHCP shall wear reusable or disposable

protective attire during patient treatment, or whenever there is a potential for aerosol spray, splashing, or spattering of blood, OPIM, or chemicals and ~~germicidal~~ disinfectant agents. Protective attire ~~must~~shall be changed daily or between patients. Protective attire shall be changed immediately if the~~y~~ attire ~~should~~ becomes ~~moist or visibly~~ soiled with blood or OPIM. 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, Cal. Code Regs., section 5193).

(5) Hand Hygiene~~:~~ Protocols and Hand Care:

~~(6)~~(A) All DHCP shall thoroughly wash their hands with soap and water (covering all surfaces of hands and fingers) for no less than 20 seconds 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, with an alcohol concentration between 60-95%, may be used as an alternative to soap and water. An alcohol-based hand rub shall be used according to the manufacturer's instructions. Hands shall be ~~thoroughly dried~~completely dry before donning gloves in order to prevent promotion of ~~bacterial~~ microbial growth and washed again immediately after glove removal.

(B) A DHCP shall refrain from providing direct patient care and from handling patient care equipment if hand conditions such as the presence of lesions, rash, or weeping dermatitis are present that may render DHCP or patients more susceptible to opportunistic infection or exposure.

~~(7) All 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~~.

(6) Gloves:

~~(8)~~(A) Medical examination gloves shall be worn by DHCP whenever there is contact with mucous membranes, blood, OPIM, and during all pre-clinical, clinical, post-clinical, and laboratory procedures. Medical examination gloves are disposable, synthetic single-use only items. Gloves shall be replaced when torn or punctured, upon completion of dental treatment, and before leaving laboratories or areas of patient care activities.

(B) Chemical and puncture-resistant utility gloves shall be available at the point of use and worn by DHCP for cleaning, sterilization, and disinfectant procedures. Chemical and puncture-resistant utility gloves shall be cleaned and disinfected or

sterilized in accordance with the manufacturer's instructions. Disposable utility gloves shall be disposed of after each use.

(C) When processing contaminated sharp instruments, needles, and devices, DHCP shall wear ~~heavy-duty~~chemical and puncture-resistant utility gloves ~~to prevent puncture wounds~~. Utility gloves shall be cleaned and sterilized in accordance with the manufacturer's instructions after each use.

(D) Gloves ~~must~~shall be discarded under any of the following circumstances:

(i) when torn or punctured~~,~~;

(ii) upon completion of dental treatment when using medical examination gloves;~~,~~ and,

(iii) before leaving laboratories or areas of patient care activities when using medical examination gloves.

(E) All DHCP shall perform hand hygiene protocols and hand care procedures specified in paragraph (5) before donning gloves and after removing and discarding medical examination gloves. Medical examination ~~G~~gloves shall not be washed before or after use, or reused.

(7) Needle and Sharps Safety:

~~(9)~~(A) 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.

(B) 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.

(8) Sterilization and Disinfection:

~~(10)~~(A) All ~~germicides must~~ products used to clean or disinfect items or surfaces shall be used in accordance with intended use and label instructions.

~~(11)~~(B) Standard precautions for disinfection and sterilization shall be performed in the following order:

(i) first, use appropriate hand hygiene protocols and hand care in accordance with paragraph (5);

(ii) second, ~~C~~clean~~ing must precede~~ items or surfaces prior to any disinfection or sterilization process; and,

(iii) third, use the disinfection or sterilization standards required by this section. ~~Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions~~ Disinfection procedures shall include use of a Cal/EPA-registered product with an applicable disinfection classification in accordance with paragraph (6) of subsection (a) to disinfect items.

~~(12)~~(C) 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 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. These instruments, items, and devices~~,~~ shall remain sealed and stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the treatment facility. If stored, sterilized packaging is compromised (e.g., wet, torn, or punctured), the instruments shall be recleaned, packaged in new wrap, and sterilized again before use.

~~(13)~~(D) Semi-critical instruments, items, and devices shall be pre-cleaned, packaged or wrapped, and sterilized after each use. Methods of sterilization include steam under pressure (autoclaving), 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. These packages or containers shall remain sealed and shall be stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the treatment facility. If stored, sterilized packaging is compromised (e.g., wet, torn, or punctured), the instruments shall be recleaned, packaged in new wrap, and sterilized again before use.

~~(14)~~(E) Non-critical surfaces and patient care items shall be cleaned and disinfected after every use with a ~~California Environmental Protection Agency (~~Cal/EPA~~)~~-registered hospital disinfectant (low-level disinfectant) spray or wipe ~~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.

~~(15)~~(F) All high-speed dental hand pieces, low-speed hand pieces, rotary components, including the motor, 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.

~~(16)~~(G) Single use critical, semi-critical, and non-critical disposable items such as scalpel blades, 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.

~~(17)~~(H) 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) with results confirmed by either authorized DHCP or an independent laboratory. Test results shall be documented and maintained for 12 months.

(I)(i) A chemical indicator shall be used inside every sterilization package to verify that the sterilizing agent has penetrated the package and reached the instruments inside. If the internal chemical indicator is not visible from the outside of the package, an external chemical indicator shall also be used.

(ii) The chemical indicator shall be inspected immediately when removing packages from the sterilizer; if the chemical indicator did not register that the sterilizing agent has penetrated the package, the instruments shall be repackaged and sterilized again.

(9) Irrigation:

~~(18)~~(A) Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone.

(B) When performing procedures on exposed dental pulp, water or other irrigation solutions shall be sterile or contain disinfecting or antibacterial properties.

(C) Sterile coolants/irrigants ~~must~~shall be delivered using a sterile delivery system.

(10) Treatment Facilities:

~~(19)~~(A) If non-critical items or clinical contact surfaces likely to be contaminated ~~are~~ or manufactured in a manner preventing cleaning and disinfection, they shall be ~~protected~~physically covered with disposable impervious barriers approved by the FDA and designed by the manufacturer for that purpose. Disposable barriers shall be changed when visibly soiled or damaged and between patients.

~~(20)~~(B) 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~~disinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use an intermediate-level disinfectant if visibly contaminated with blood. Use disinfectants in accordance with the manufacturer's instructions.

(C) 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 procedures shall be clearly labeled, and DHCP shall follow all ~~material~~ safety data sheet (~~M~~SDS) handling and storage instructions.

~~(21)~~(D) 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, or other devices. The dental unit lines and devices shall be flushed ~~between~~ after each patient for a minimum of twenty (20) seconds. Dental unit water lines shall be monitored or tested routinely in accordance with manufacturer's instructions.

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

(11) Lab Areas:

~~(23)~~(A) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a sterilized or new, disposable rag-wheel shall be used for each patient. ~~Devices~~

(B) Laboratory equipment, including handpieces, polishing (rag) wheels, grinding wheels, and laboratory burs, used to polish, trim, or adjust contaminated appliances and ~~intraoral~~ prosthetic devices shall be cleaned, disinfected ~~or sterilized~~, properly packaged or wrapped, and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item as specified in subparagraph (D) of paragraph (8), or if a single-use item, disposed of in accordance with subparagraph (G) of paragraph (8).

(C) Laboratory equipment shall be stored in a manner consistent with the same storage practices as a semi-critical item as specified in subparagraph (D) of paragraph (8).

~~(24)~~(D) All intraoral items such as impressions, bite registrations, and prosthetic and orthodontic appliances shall be cleaned and disinfected with ~~a~~an Cal/EPA-registered intermediate-level disinfectant before and after 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.

(12) Respiratory Hygiene/Cough Etiquette: Measures shall be implemented to contain respiratory secretions and to prevent droplet and fomites transmission of respiratory pathogens, especially during seasonal outbreaks of viral respiratory infections such as influenza, RSV, adenovirus, parainfluenza virus, or SARS-CoV-2 (COVID-19) virus, as follows.

(A) Prominently posting at least one sign at every point of entrance and reception or registration desk of the treatment facility, accessible to public view, in which case the signs shall be in at least 12-point type font. The signs shall contain instructions to patients who cough or sneeze at the treatment facility to do at least all of the following: (i) cover their mouths or noses when coughing or sneezing; (ii) use and dispose of tissues in waste receptacles; and, (iii) wash hands with soap and water or use alcohol-based hand rub after coughing or sneezing.

(B) Provide tissues and no-touch receptacles (e.g. foot-pedal operated lid or open plastic-lined waste basket) for disposal of tissues.

(C) Have soap, warm running water, and paper towels, or alcohol-based hand rub available for use in or immediately adjacent to waiting areas.

(D) Offer masks to coughing or sneezing patients or other persons when they enter the treatment facility.

(E) Provide distance between patients who cough or sneeze in common waiting areas. If available, facilities shall place these patients in a separate area while waiting for care.

(c) DHCP who are employers of other DHCP shall provide those personnel with a training program on the minimum standards required by this section and the infection control plan specified in paragraph (2) of subsection (b). Such training program shall be provided at no cost to the personnel and during working hours in accordance with all of the following.

(1) The training program shall be provided as follows:

(A) Prior to assignment to tasks where OPIM exposure may take place; and,

(B) Within one year of the date of the DHCP's previous training thereafter.

(2) DHCP employers shall provide additional training prior to or by the effective date of any change to the minimum standards in this section or to the written infection control plan specified in paragraph (2) of subsection (b). The additional training may be limited to addressing the changes in the standards required by this section or the written infection control plan.

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

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[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.