TITLE 16. DENTAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

INITIAL STATEMENT OF REASONS

Hearing Date: October 11, 2010

Subject Matter of Proposed Regulations: Minimum Standards for Infection Control

Section(s) Affected: Title 16, Division 10, California Code of Regulation, Section 1005

Specific Purpose of Each Adoption, Amendment, or Repeal:

The Dental Board of California proposes to amend Section 1005 of Division 10 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to revise existing infection control regulations to conform with recent changes in the Centers for Disease Control (CDC) "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008" (hereinafter CDC guidelines) and incorporate revisions made to regulations of the California Division of Occupational Safety and Health. The amendments clarify who must comply with the regulations and identify equipment to be used.

Proposed changes, by section, are more specifically identified as follows:

Amend Section 1005(a)(1)
This section has been amended to conform with changes to the CDC guidelines. The amended text specifies that the defined "standard precautions" apply to all patients treated in a dental office, regardless of actual or suspected infectious status, to ensure all patients receive protection from infectious diseases, and to ensure consistent precautions are utilized in the dental healthcare field. These precautions are applicable in any setting in which healthcare services are performed, including settings outside a dental office or clinic such as public health fairs or school screenings. The amendments specify infection prevention practices and clarify that the practices are mandatory, rather than recommended.

Amend Section 1005(a)(2)
This section has been amended to specify all devices and items that are used to penetrate soft tissue or bone are included within the definition of "critical items". This expanded definition ensures that all devices and items, not only instruments, used for such procedures meet the same infection control requirements to ensure patient protection. The term "devices" was added to provide consistency throughout the section.

Amend Section 1005(a)(3)
This section has been amended to specify that all instruments, devices, and items used intra-orally and come in contact with oral mucous membranes, non-intact skin, and

other potentially infectious materials (OPIM) are included within the definition of “semi-critical items”. This expanded definition ensures that all devices and items, not only instruments, used within the oral cavity meet the same infection control to ensure patient protection.

Amend Section 1005(a)(4)
This section has been amended to specify that all instruments, devices, equipment, and surfaces that contact soil, debris, saliva, blood, OPIM, and intact skin, but do not contact oral mucous membranes, are included within the definition of “non-critical items”. Adding the terms “soil”, “debris”, “saliva”, “blood”, and “OPIM” addresses extra-oral items indirectly contaminated during clinical procedures. According to the CDC, non-critical items pose the least risk of transmission of infection. Contacting only intact skin serves as an effective barrier to infectious microorganisms.

Amend Section 1005(a)(5)
This section has been amended to provide clarity.

Amend Section 1005(a)(6)
This section has been amended to provide clarity.

Amend Section 1005(a)(8)
This section has been amended to define “Germicide” as a chemical agent used to disinfect contaminated items and surfaces. This definition was added to provide consistency with the other definitions within the section. This definition conforms to the current CDC guidelines.

Amend Section 1005(a)(9)
This section has been amended to redefine “Sterilization” as a validated process used to rid a product of all forms of viable microorganisms. The definition has been expanded to ensure consistency with the above definitions and to conform to the current CDC guidelines.

Adopt Section 1005(a)(10)
This section has been added to include the definition for “Cleaning” as the manual or mechanical removal of soil, debris, and OPIM from objects and surfaces with the use of water and detergent or enzymatic products. The section requires cleaning before the disinfection or sterilization process and requires products used to clean items or surfaces prior to disinfection to be used according to label instructions. If objects and surfaces are not cleaned first, then a successful disinfection process can be compromised. This section has been added for to provide consistency with the other definitions within the section and to conform to the current CDC guidelines.

Amend Section 1005(a)(10)
This section has been renumbered to be Section 1005(a)(11). This section has been amended to further define “Personal Protective Equipment” as clothing or equipment for protection against an infectious hazard in addition to existing text which specifies the

equipment. The amended definition also includes the acronym “PPE”. This acronym is used throughout the section and needs to be defined to provide clarity. It is a standardized term used in educational and professional environments. The use of personal protective equipment is imperative to protect against infection of potentially infectious microbes.

Amend Section 1005(a)(11)
This section has been renumbered to be Section 1005(a)(12).

Amend Section 1005(a)(11)(A)
This section has been renumbered to be Section 1005(a)(12)(A) and contains technical and grammatical amendments.

Amend Section 1005(a)(11)(B)
This section has been renumbered to be Section 1005(a)(12)(B) and contains technical and grammatical amendments.

Amend Section 1005(a)(11)(C)
This section has been renumbered to be Section 1005(a)(12)(C) and contains technical and grammatical amendments.

Adopt Section 1005(a)(13)
This section has been added to include the definition of “Dental Healthcare Personnel” (DHCP) as paid and non-paid personnel providing dental healthcare who may be occupationally exposed to infectious materials. DHCP is further defined to include dentists, dental hygienists, dental assistants, dental laboratory technicians, students and trainees, contractual personnel, and others not directly involved with patient care buy potentially exposed to infectious materials. The addition of this section and acronym conform to current CDC guidelines and provide consistency throughout the section.

Amend Section 1005(b)
This section has been amended to specify all DHCP are required to comply with infection control precautions and enforce specified minimum precautions to minimize the transmission of pathogens in health care settings as mandated by the California Division of Occupational Safety and Health (Cal-DOSH). The board requires that all licensees adhere to the same minimum standards for infection control to ensure patient safety.

Repeal Section 1005(c)
This section has been repealed. Provisions of subsection (c) have been incorporated into subsection (b) to provide clarity and consistency.

Amend Section 1005(c)(1)
This section has been renumbered to be Section 1005(b)(1).

Amend Section 1005(c)(2)

This section has been renumbered to be Section 1005(b)(2). This section has been amended to require written protocols to be developed, maintained, and updated for proper instrument processing, operatory cleanliness, and management of injuries. The written protocol is required to be available to all dental health care personnel in the dental office. As amended, a dental facility may choose to utilize professional organizations or contractors to assist in developing the protocol requirement. By adding a maintenance provision, written protocols can be updated within the dental facility based on advances in equipment, products, and procedures.

Amend Section 1005(c)(3)

This section has been renumbered to be Section 1005(b)(3).

Amend Section 1005(c)(4)

This section has been renumbered to be Section 1005(b)(4). This section has been amended to require all DHCP to wear surgical facemasks with plastic face shields or protective eyewear when there is potential for aerosol spray, splashing or spattering of droplet nuclei, blood, chemical or germicidal agents other potentially infectious material. Puncture-resistant utility gloves and other personal protective equipment are required to be worn when handling hazardous chemicals. The puncture-resistant gloves offer more protection that patient exam gloves while using hazardous chemicals. Masks are required to be changed and disposed after each patient treatment. Face shields and protective eyewear are required to be cleaned, disinfected, or disposed after each patient treatment. This amendment was made to include the terms “aerosol spray” and “droplet nuclei” to conform to the current CDC guidelines and the use of standard precautions. The term “if contaminated” has been struck in order to eliminate the potential for assuming equipment has or has not been contaminated. Personal protective equipment should be used during procedures involving hazards other than blood or OPIM. Masks and protective eyewear should be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated item in order to prevent occupational exposure to infectious agents.

Amend Section 1005(c)(5)

This section has been renumbered to be Section 1005(b)(5). This section has been amended to require gowns to be worn for disinfection, sterilization, and housekeeping procedures when germicides are being used or while handling contaminated items. The amendments also require licensees to wear reusable or disposable protective attire when there is a potential for aerosol spray, splashing, or splattering of blood, OPIM, or chemical and germicidal agents. All personal protective equipment used during patient care is required to be removed when leaving laboratories or areas where patient care is provided. These amendments conform to the current CDC guidelines. These amendments provide specificity for dental healthcare personnel regarding the minimum standards for the use of personal protective equipment to prevent contamination of infectious diseases.

Amend Section 1005(c)(6)

This section has been renumbered to be Section 1005(b)(6). This section has been amended to replace the term “health care workers” with “dental healthcare personnel” to provide clarity and consistency within the section. The amendment also includes a requirement for hands to be thoroughly dried prior to wearing gloves and washed immediately after removing gloves to prevent bacterial growth. The necessity of hand washing is not eliminated by wearing gloves. Gloves have the potential to have small, unapparent defects and can be torn during patient treatment, thus contaminating hands. This increases the risk of contamination and exposure to microorganisms. Bacteria rapidly multiply in moist environments, such as gloves, therefore it is necessary to thoroughly dry hands before donning on gloves.

Amend Section 1005(c)(7)

This section has been renumbered to be Section 1005(b)(7). This section has been amended to replace the term “health care workers” with “dental healthcare personnel” to provide clarity and consistency within the section.

Amend Section 1005(c)(8)

This section has been renumbered to be Section 1005(b)(8). This section has been amended to require medical exam gloves to be worn when there is contact with mucous membranes, blood, OPIM, or germicidal agents and during all pre-clinical, clinical, post-clinical, and laboratory procedures. Dental health care personnel are required to wear heavy-duty utility gloves while cleaning sharp instruments. This requirement is necessary to prevent puncture wounds. The requirement to discard torn or punctured gloves and the requirement to follow hand hygiene procedures prior to donning gloves has been added to prevent the spread of infectious diseases. The term “potential” has been struck because it gives the appearance that healthcare personnel can choose to whether or not to wear glove based on their interpretation of “potential harm”. These amendments clearly define parameters for which gloves should be worn. Unless the current language is amended, there is risk of dental healthcare personnel continuing to remove and re-use gloves for the same patient.

Adopt Section 1005(c)(9)

For the purpose of clarity, this regulatory language was repealed from subsection (c)(13) and has been adopted in new subsection (b)(9) under a new heading for “Needles and Sharps Safety”. Safety while handling needles and other sharps are imperative for the protection of the health care provider and patient from infectious diseases. Because this is such an important aspect of infection control, it is appropriate to have it included under a specific heading rather than be included in provisions for “Sterilization and Disinfection”.

Amend Section 1005(c)(9)

This section has been renumbered to be Section 1005(b)(10). This section has been amended to require critical items to be pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization have been defined to include steam under pressure, chemical vapor and dry heat. If a semi-critical item is heat sensitive, then it is

required to be cleaned with high-level disinfection in the form of a package or being wrapped prior to sterilization. Packages and containers are required to remain sealed and stored to prevent contamination. Reiterating the pre-cleaning process prior to sterilization procedures provides consistency and clarity to licensees following the standard precautions to minimize the transmission of infectious diseases.

Amend Section 1005(c)(10)
This section has been renumbered to be Section 1005(b)(11). This section has been amended to require semi-critical items to be pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization have been defined to include steam under pressure, chemical vapor and dry heat. If a semi-critical item is heat sensitive, then it is required to be cleaned with high-level disinfection in the form of a package or being wrapped prior to sterilization. Packages and containers are required to remain sealed and stored to prevent contamination. Reiterating the pre-cleaning process prior to sterilization procedures provides consistency and clarity to licensees following the standard precautions to minimize the transmission of infectious diseases.

Adopt Section 1005(c)(12)
This section has been added to require non-critical surfaces and patient care items to be cleaned and disinfected with an EPA-registered hospital disinfectant effective against HBV and HIV. This section also requires visibly contaminated items to be disinfected with an EPA-registered hospital disinfectant with a tuberculocidal claim. The Dental Board's minimum standards for infection control do not currently provide regulatory requirements for the proper handling of non-critical items. This proposed addition provides clarity to dental healthcare personnel regarding the disinfection standards for non-critical items.

Amend Section 1005(c)(11)
This section has been renumbered to be Section 1005(b)(13). This section has been amended to require high-speed dental hand pieces, low-speed dental hand pieces, rotary components and dental unit attachments to be packaged and sterilized in a manner consistent with the same sterilization practices as semi-critical items. The term "used intra-orally" was removed due to the common practice of adjusting removable prosthesis outside the oral cavity. It is imperative for the dental office to practice consistent sterilization processes to prevent contamination of infectious diseases.

Amend Section 1005(c)(12)
This section has been renumbered to be Section 1005(b)(14). This section has been amended to require single use disposable items to be used for a single patient and then discarded. Using the term "item" instead of "instrument" allows for a broader scope of disposable references, such as gloves, to be included. Certain personal protective equipment has not been adequately defined as "single-use" and this amendment provides clarity.

Repeal Section 1005(c)(13)
For the purpose of clarity, this section has been repealed and has been adopted in new subsection (b)(9) under a new heading for “Needles and Sharps Safety”. Safety while handling needs and other sharps are imperative for the protection of the health care provider and patient from infectious diseases. Because this is such an important aspect of infection control, it is appropriate to have it included under a specific heading rather than be included in provisions for “Sterilization and Disinfection”.

Amend Section 1005(c)(14)
This section has been renumbered to be Section 1005(b)(15). This section has been amended to require all sterilization devices to be tested each week to verify proper functioning of the sterilization cycle. The test results are required to be documented and maintained for twelve months. It is imperative for sterilization devices to be maintained and function properly to avoid the spread of infectious diseases.

Amend Section 1005(c)(15)
This section has been renumbered to be Section 1005(b)(16).

Amend Section 1005(c)(16)
This section has been renumbered to be Section 1005(b)(17). This section has been amended to require non-critical items manufactured in a way preventing cleaning and disinfection to be protected with disposable impervious barriers. The amendment requires disposable barriers to be changed when visibly soiled or damaged an in between patients. Products used to clean items or surfaces are required to be labeled and follow all material safety data sheet handling and storage instructions. Non-critical items and surfaces present the least risk of transmission of infectious material by contacting only intact skin. Intact skin serves as an effective barrier to microorganisms. Sometimes it can be difficult to clean non-critical items or could cause damage, therefore the use of disposable impervious barriers is a preferred alternative method to prevent contamination. Disposable impervious barriers should be changed when soiled or damaged and in between patients to prevent contamination of infectious materials.

Amend Section 1005(c)(17)
This section has been renumbered to be Section 1005(b)(18). The amendment adds the title of the California Environmental Protection Agency to provide clarity to the existing acronym Cal-EPA.

Amend Section 1005(c)(18)
This section has been renumbered to be Section 1005(b)(19). This section has been amended to require dental unit lines and devices to be purged with air or flushed with water for a minimum of two minutes at the beginning of each work day. This is required to be done prior to attaching hand pieces, scalers, air water syringe tips or any other device. The dental unit lines and devices are required to be flushed in between each patient. The CDC reported that material from patient care, such as oral microorganisms, blood, and saliva, can enter the dental unit lines during treatment. The CDC recommends devices that are connected to the dental unit lines and enter patient’s

mouths should be flushed with air or water for a minimum of twenty to thirty seconds after each patient treatment in order to flush out the material from patient care.

Amend Section 1005(c)(19)
This section has been renumbered to be Section 1005(b)(20).

Amend Section 1005(c)(20)
This section has been renumbered to be Section 1005(b)(21). This section has been amended to require disinfected and sterilized devices to be stored in a manner that prevents contamination. This amendment provides consistency with language previously used regarding sterilization and disinfection.

Amend Section 1005(c)(21)
This section has been renumbered to be Section 1005(b)(22). This has been amended to clarify that all intraoral items are required to be cleaned and disinfected with an intermediate-level disinfectant before use in the laboratory or used in the patient's mouth to prevent the spread and contamination of infectious diseases and ensure patient protection.

Amend Section 1005(d)
Business and Professions Code Section 1680(ad) requires the Dental Board of California and the Dental Hygiene Committee of California to review the minimum standards for infection control annually and establish a consensus. This section has been amended to conform to the statutory requirement.

Factual Basis/Rationale
Business and Professions Code Section 1680(ad) requires the board to annually review and if necessary, adopt new regulations to ensure minimum standards for infection control are adequately addressing patient safety needs. The Dental Board's Infection Control Committee has reviewed the regulations for clarity of language, necessity for amendments, and consistency with other governing agencies, such as CAL-OSHA, Cal-EPA, and the Centers for Disease Control. The Dental Board of California and the Dental Hygiene Committee of California have worked together and have established a consensus on the proposed regulatory amendments to the minimum standards for infection control.

Underlying Data
1) August 28, 2008 Dental Bureau Advisory Committee Meeting Minutes
2) November 21, 2008 Dental Bureau Advisory Committee Meeting Minutes
3) July 22, 2009 Infection Control Committee Meeting Minutes
4) July 23, 2009 Dental Board of California Meeting Minutes
5) November 9, 2009 Infection Control Committee Meeting Minutes
6) November 10, 2009 Dental Board of California Meeting Minutes
7) February 25, 2010 Infection Control Committee Meeting Minutes
8) February 26, 2010 Dental Board of California Meeting Minutes
9) May 6, 2010 Dental Board of California Meeting Minutes

10) July 26, 2010 Dental Board of California Meeting Minutes
11) Centers for Disease Control (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
12) California Code of Regulations Title 8, Section 5193

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Specific Technologies or Equipment

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

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulations.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

1. Do not seek a regulatory change.

Rejected: The Board is required by law to annually review infection control guidelines and make necessary changes to minimize the risk of transmitting bloodborne infectious diseases while providing dental health care.