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California Infection Control Regulations for Dental Professionals

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ABSTRACT Infection control regulations that affect dental professionals come from several regulatory agencies and are increasingly complex. Staying up to date on changes and the overlapping requirements can challenge a busy dental practice. This article reviews the current regulations in California and suggests methods for ensuring every dental office is in compliance.

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Numerous government agencies regulate infection control practices for dental offices. Depending on the authority of the agency, the focus may be on employee safety, patient safety, environmental safety or any combination of the above.[1,2,3] In addition to regulations, the Centers for Disease Control and Prevention (CDC) issues infection control recommendations for dental health care personnel (DHCP).[4,5,6] The complexity of these regulations and recommendations and the number of agencies involved may present a challenge to DHCP when faced with the need to ensure compliance within their offices or clinics. This article provides a broad overview of the requirements for each of the regulatory agencies involved in infection control for dentists in California.

Occupational Safety and Health Administration (OSHA)

This federal agency has the authority to enforce regulations intended to provide a safe and healthy workplace to the working men and women of the United States. In addition to the federal agency, 26 states, Puerto Rico and the Virgin Islands have OSHA-approved state plans. California is one of the states that administers its own OSHA program (Cal/OSHA) within the California Department of Industrial Relations. Cal/OSHA regulations must be at least as strict as the federal regulations, but can and do have additional requirements.

Among the many regulations enforced by Cal/OSHA is the blood-borne pathogens standard.[7]

TABLE 1

Summary of Requirements of the Cal/OSHA Blood-Borne Pathogens Standard and an Overview of the Major Elements

Requirement	Major Elements
Exposure control plan	Written policy with exposure determination, schedule and method of implementation of the regulation, exposure incident follow-up and Sharps Injury Log procedure. Reviewed and updated at least annually. Available in the workplace to all employees with exposure to blood and other potentially infectious materials (OPIM).
Work practice controls	Reduces the likelihood of exposure by altering a procedure (e.g., prohibiting two-handed needle recapping, avoiding transfer of syringe with used uncapped needle from operator to assistant).
Engineering controls	Controls that isolate or remove a blood-borne pathogens hazard (e.g., sharps containers, safety devices). A device must have a built-in physical attribute to be considered an engineered sharps injury protection device.
Regulated medical waste	Sharps discarded immediately or as soon as possible after use. Sharps containers close as feasible to the immediate area where sharps are used. Use of appropriate containers, labeling with the biohazard symbol and handled in accordance with state and federal regulations.
Cleaning and decontamination	Written methods and schedules for cleaning and decontamination of work surfaces. Cleaned and disinfected immediately or as soon as feasible after a spill of blood or OPIM, completion of procedure and then end of work shift if contamination has occurred since last cleaning. Removal and replacement of barriers as soon as feasible when contaminated.
Hand hygiene	Provide hand washing facilities. Hand washing immediately or as soon as feasible after glove removal or other personal protective equipment (PPE) or after contact with blood or OPIM.
Contaminated laundry	Handled as little as possible. Bagged at the location of use. Transported in container labeled or color-coded as biohazard. Handled with protective gloves and other PPE as appropriate.
Personal protective equipment (PPE)	Must be provided, repaired, disposed, replaced and laundered by the employer at no cost to the employee. PPE includes gloves, masks, eye protection, face shields, respirators, gowns, aprons and other protective body clothing as appropriate to prevent occupational exposure. Employer must ensure the use of PPE by employees.
Hepatitis B vaccination	Offered within 10 days of assignment to all employees with occupational exposure, unless they have previously completed the vaccine series, have documented immunity or have medical contraindications for the vaccine. Employees who decline the vaccine must sign a specific vaccine declination.
Post-exposure evaluation and follow-up	Confidential medical evaluation and follow-up to be made available to any employee reporting an exposure incident. Testing of source patient for HIV, HBV and HCV if consent is obtained. Employer to provide post-exposure prophylaxis (if indicated), counseling and evaluation of reported illnesses. Collect information related to the incident and obtain the evaluating health care professional's written opinion. Maintain in employee's medical record.
Labeling	Biohazard warning labels affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM or containers used to store, transport or ship blood or OPIM.
Information and training	Training provided at initial assignment and at least annually thereafter. Additional training when new controls, tasks or procedures are introduced that affect the employee's occupational exposure. There are 14 identified elements that must be included in the training.
Record keeping	Medical records must include the name and Social Security number of the employee, a copy of the hepatitis B vaccine status and exposure incident information. Maintained confidential and for the length of employment plus 30 years. Training records include dates of training, contents or summary, name and qualifications of trainer, and names and job titles of attendees. Maintained for three years from the date of training.

Note: This table is a summary of the major requirements of the Cal/OSHA Blood-Borne Pathogens Standard and should not be used as a guide for complete compliance. Refer to the regulatory standard for more detailed information.

This standard is intended to ensure employers provide policies, devices and equipment that will prevent employees' contact with patient blood or other potentially infectious materials (OPIM). The focus of this rule is solely employee safety. Therefore, there are some essential infection control practices, such as instrument sterilization, not addressed by this standard. Additional requirements are enforced by other agencies described in this article.

The blood-borne pathogens standard requires employers to implement two types of controls to prevent occupational exposure to blood and OPIM. The first are engineering controls, which isolate or remove the hazard. Cal/OSHA requires the use of engineered sharps injury protection (ESIP) devices when available. ESIP may include items such as self-sheathing needles, needleless systems for IV sedation, scalpels with retractable blades and any other safety device that isolates or removes a contaminated sharp. ESIP must be provided to employees unless it is not available in the marketplace, it will jeopardize patient safety or the success of the procedure, or if the employer can demonstrate that there is not reliable information on the safety performance of the device. If there is not reliable safety information about a specific safety device, the employer is required to actively evaluate the product to determine if it will reduce the risk of exposure incidents in the workplace.

Work practice controls alter the way in which a task is performed to make it inherently safer. An example of a work practice control is using a one-handed scoop technique or needle cap holder to resheath dental anesthetic needles. A list of the major requirements of the Cal-OSHA Blood-Borne Pathogens Standard can be found in **TABLE 1**.

California Dental Practice Act

The Dental Practice Act (DPA) regulates the practice of dentistry in the state of California. Section 1005 of Title 16 in the California Code of Regulations contains the Minimum Standards for Infection Control. Enforced by the Dental Board of California (DBC), these infection control regulations are intended to protect the health and safety of the public. Although there are numerous areas of overlap with the Blood-Borne Pathogens Standard, such as the use of personal protective equipment (PPE), hand hygiene and regulated medical waste, there are additional requirements in this regulation not found in the Blood-Borne Pathogens Standard.

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The DPA requires that standard precautions be practiced in the care of all patients.[2] Standard precautions were first suggested by the CDC in 1996 to update and replace universal precautions, which had emphasized the need to consider all blood and body fluids that may contain blood as potentially infected with hepatitis B, HIV, hepatitis C or any other blood-borne disease.[8] Standard precautions expand universal precautions and clarify that all body fluids, excretions and secretions with the exception of sweat should be considered potentially infectious regardless of whether or not they contain blood. Standard precautions include contact involving patients' blood and OPIM with non-intact skin and mucous membranes, in addition to percutaneous injuries with contaminated sharp instruments.

Programmatic elements required by the DPA include development of a written program that addresses instrument processing, operatory cleanliness and management of injuries. This written program may be combined with the Cal/OSHA required exposure control plan, provided that all requirements of both regulations are addressed and that it is made accessible to employees in the workplace. It is also required that a copy of the Minimum Standards for Infection Control be conspicuously posted in each dental office. A copy of the Minimum Standards is available on the DBC website at dbc.ca.gov.

Personal Protective Attire

The Minimum Standards require the use of PPE for disinfection, sterilization and housekeeping procedures involving the use of germicides or handling of contaminated items. This is in addition to wearing PPE in connection with patient care procedures. Medical gloves are required during preclinical, clinical, postclinical and laboratory procedures. Heavy-duty utility gloves, in addition to other task-specific PPE, are required when handling contaminated sharp items after patient care to avoid percutaneous injury. Surgical facemasks in combination with face shields or protective eyewear and protective attire such as a gown or lab coat are required for procedures that may produce spray, splashing or spattering of blood, OPIM

or chemicals, such as disinfectants. Masks must be removed and discarded after each patient and a new mask used for subsequent patient contact.

Hand Hygiene

The regulation specifies that DHCP must wash hands with soap and water at the start and end of each workday and whenever hands are visibly soiled. In all other instances, it is acceptable to use alcohol-based hand sanitizer for hand hygiene procedures, which must be done before placing gloves prior to treating each patient. Hand sanitizers act as excellent antimicrobial agents, but do not physically clean skin, making them unsuitable for use on hands that contain any type of soil or debris.[9] When gloves are removed, hand hygiene must be performed again using either soap and water or an alcohol-based hand sanitizer, depending on the presence or absence of debris on the hands.

Sterilization and Disinfection

To determine which instruments and devices require sterilization and which may be disinfected, it is necessary to understand Spaulding Classification of critical, semicritical and noncritical devices (TABLE 2). Proper cleaning of instruments and devices must always precede sterilization or disinfection. Heat sterilization must be used for all critical and semi-critical items, unless they cannot be heat sterilized. In that case, they would need to be either sterilized or high-level disinfected using an immersion disinfectant registered as a high-level disinfectant or chemical sterilant.[2] It should be noted that some high-level disinfectants/sterilants present an inhalation hazard to employees, and controls such as additional ventilation and proper containment may be required when using these products.[10] All critical and semicritical items must be packaged for sterilization and remain sealed and stored to prevent contamination. All handpieces and their components are semicritical devices and therefore must be heat sterilized.[2] Using a surface disinfectant or barrier without heat sterilization for handpieces and other heat stable intraoral devices is not acceptable. If it is necessary to use an immersion high-level disinfectant/sterilant, then the item must be packaged or wrapped upon completion of the process.[2] The regulation requires that all packages of sterile instruments be marked with the date of sterilization and also the specific sterilizer if more than one is used by the practice. When marking paper-plastic pouches using a pen, markings should be made only on the plastic side of the pouch.[11] If using marking pens to label wrapped packs, markings should be made on the indicator tape. Only marking pens with nontoxic ink should be used since it is possible for the toxins from ink to bleed out onto the packaging or instruments.[11]

Biological indicator (BI) tests are required at least weekly for each sterilizer in the practice. These tests, sometimes referred to as spore tests, consist of organisms (spores) that are highly resistant to the heat sterilization process. The BI should only be used as directed in the manufacturer's instructions for use, including placement of the BI in the load, handling, incubation and reading.[11] All California dental offices must maintain BI test results for 12 months.[2]

Clinical surfaces and noncritical patient care items must be cleaned and then disinfected using a Cal/EPA-registered hospital disinfectant. When blood is present, the disinfectant must have a tuberculocidal claim, which indicates it is an intermediate-level disinfectant. If no blood is present, then it is acceptable to use a low-level disinfectant, which will not be labeled as tuberculocidal, but will be labeled as effective against Hepatitis B virus (HBV) and HIV. The manufacturer's instructions for any mixing (for concentrated solutions), methods of application, PPE, contact time and precleaning should be carefully reviewed and followed.

Other Requirements

Single-use disposable items must be used for one patient only and then discarded. The DHCP should not attempt to reprocess items identified by the manufacturer as "single-use only" or where the manufacturer does not provide reprocessing instructions. This includes items such as prophylaxis cups

TABLE 2

Infection Control Categories of Patient-Care Instruments

Category	Definition	Dental Instrument or Item
Critical	Penetrates soft tissue, contacts bone, enters into or contacts the bloodstream or other normally sterile tissues	Surgical instruments, periodontal scalers, scalpel blades
Semicritical	Contacts mucous membranes or non-intact skin; will not penetrate soft tissue, contact bone, enter into or contact the bloodstream or other normally sterile tissue	Dental mouth mirror, amalgam condenser, reusable dental impression trays, dental handpieces*
Noncritical	Contacts intact skin	Radiograph head/cone, blood pressure cuff, facebow, pulse oximeter

*Although dental handpieces are considered a semicritical item, they should always be heat-sterilized between uses and not high-level disinfected.

Adapted from: CDC. Guidelines for Infection Control in Dental Health Care Settings – 2003.

and brushes, disposable prophylaxis angles, plastic high-speed evacuation tips, saliva ejectors and other items labeled as "single-use only."[2]

Dental unit waterlines that are not treated by chemical disinfection or filtration have long been known to develop biofilm, which then contaminates the water exiting the dental devices attached to the waterlines.[12,13,14] The DPA requires that dental units and devices be purged with air and water for at least two minutes at the beginning of the workday before attaching handpieces, scaler tips, air/water syringe tips or other devices. Between patients, flushing for at least 20 seconds is required.[2] This should be done before detaching devices from the waterlines.[4] When performing surgical procedures involving soft tissue or bone, sterile coolants/irrigants must be used. The sterile solution must be delivered using a sterile delivery system. Placing sterile water or sterile saline in a dental unit water reservoir would not meet the requirement unless the reservoir, all tubing and attachments were also sterile.

All DHCP in California must complete at least two hours of continuing education in Minimum Standards for Infection Control every two years, in addition to any other content required by the DBC.

California Medical Waste Management Act

Medical waste regulations are enforced by the California Department of Public Health (DPH) through their Medical Waste Management Program (MWMP). The regulations related to medical waste were last updated in January 2016 and are contained in California Health and Safety Code sections 117600 – 118360. The regulation divides medical waste generators into two categories: those that produce less than 200 pounds per month of medical waste (small quantity generators) and those that generate 200 pounds or more of medical waste per month (large quantity generators). Most dental practices should qualify as small quantity generators.

Medical waste includes biohazardous waste, defined by the MWMP to include waste that contains recognizable fluid human blood, fluid human blood products, containers or equipment containing human blood and certain animal wastes. Medical waste is also pathology waste, which includes human body parts, with the exception of teeth removed at surgery or specimens or tissues that are suspected of being contaminated with infectious agents or those that have been fixed in formaldehyde or another fixative.[3] Sharps are another type of medical waste and include contaminated needles, blades, root canal files, broken glass and other items with acute rigid corners or edges capable of cutting or piercing.[3] Intact empty anesthetic cartridges are not considered medical waste unless they contain recognizable fluid blood. Other waste such as paper towels, gauze and other articles that contain nonfluid blood are not medical waste and can be disposed of with nonregulated waste.

Pharmaceutical waste is a medical waste. Expired medications, including local anesthetic, must be collected and disposed of by an approved medical waste disposal method, usually incineration or high heat destruction.[3] Pharmaceutical waste may be combined with sharps waste if certain conditions are met. The waste must be collected in an approved container (such as a sharps container marked with the universal biohazard symbol), and the container must be

FIGURE. An approved container for collecting pharmaceutical waste combined with sharps.

labeled with either "HIGH HEAT" or "INCINERATION ONLY" on the lid and sides of the container (**FIGURE**). For small quantity generators, full containers of sharps may be stored on-site for no more than 30 days before removal for treatment or destruction. The storage limit for pharmaceutical waste is no more than 90 days after the container is ready for disposal. The container must be emptied at least once per year.[3] If sharps and pharmaceuticals are consolidated in a single container, the shorter storage limit of 30 days applies.

Some dental offices, particularly those that perform surgical procedures, may have additional requirements to collect medical waste that would include waste that contains recognizable fluid blood or blood products or any containers or equipment containing fluid human blood. This biohazard waste must be collected and contained separately from other waste. It may be contained in the patient treatment area using a biohazard bag not to exceed three pounds or one gallon. To remove it, tie the bag and place the bag into a biohazard container in the area where biohazard waste is stored. The containers must be leak resistant, have tight-fitting covers and be kept in a clean and intact condition. The containers must be labeled with the

words "biohazardous waste" or the international biohazard symbol and the word "BIOHAZARD" on the lid and all sides. The storage limits for biohazardous waste differ from that of sharps or pharmaceutical waste. If an office generates 20 pounds or more per month, it must be removed within seven days from when the waste began accumulating. If the office generates less than 20 pounds per month, it may be stored for up to 30 days from the accumulation start date.[3] The containers should be labeled with the accumulation start date to ensure it is not maintained longer than allowed by the MWMA.

Conclusions

The complexity of regulations related to infection control presents a challenge to DHCP in keeping track of changes and implementing the required practices. There are numerous sources of information, including professional dental organizations such as the American Dental Association, the California Dental Association and the Organization for Safety, Asepsis and Prevention, that may help. Continuing dental education courses are available for review of the requirements and strategies for implementation in the dental office. Other sources of information include professional journals and trade publications. The regulatory agencies often have many resources for DHCP, including copies of the regulations, sample written policies, and frequently asked questions and answers, among others. In 2016, the CDC provided a summary of infection control guidelines to help meet the basic expectations for safe care, with associated checklists to assist DHCP in determining gaps in their infection control programs and practices.[15] However, reviewing this information and making the necessary changes to policy and practice in the dental office requires the dedication of time on the part of whomever is responsible for infection control for the dental practice. Assigning responsibility to an individual to become the infection prevention or infection control coordinator for the office is an effective way to ensure that the practice remains up to date on the latest recommendations and requirements.[4,8,16,17] Although this individual can have other duties in the practice, they should be provided with ample time to review programs, attend educational seminars, periodically review the agency websites and provide training to the rest of the dental team. Periodic updates may be provided in regular staff meetings, while dedicated time should be set aside for new employee and annual training. ■

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