Facility Site Review Standards

Purpose: The Facility Site Review Standards provide the instructions, rules, regulations, parameters, and indicators for conducting Facility Site Reviews using the Facility Site Review tool. The site reviewer must use these Standards for measuring, evaluating, assessing, and making decisions.

Scoring: Site reviews include on-site inspection and interviews with site personnel. Reviewers are expected to use reasonable evidence available during the review process to determine if practices and systems on site meet review criteria. Critical Elements have a weight of two (2) points each and non-Critical Elements have a weight of one (1) point on the site review tool. Compliance levels include:

1) Exempted Pass: 90% or above *without deficiencies* in Critical Elements, Pharmaceutical or Infection Control
2) Conditional Pass: 80-89%, or 90% and above with deficiencies in either Critical Elements, Pharmaceutical or Infection Control
3) Fail: 79% and below

A corrective action plan (CAP) is required for a total score less than 90%, *OR* for a total score of 90% or above if there are deficiencies in Critical Elements, Pharmaceutical Services or Infection Control. Compliance rates are based on 170 total possible points, or on the total "adjusted" for Not Applicable (N/A) items. "N/A" applies to any scored item that does not apply to a specific site as determined by the reviewer. Reviewers are expected to determine how to ascertain information needed to complete the review. Review criteria that shall be reviewed *only* by a registered nurse (RN), nurse practitioner (NP), Certified Nurse Midwife (CNM), Licensed Midwife (LM), physician (MD), or physician assistant (PA) is labeled "**RN/NP/CNM/LM/MD/PA".**

Directions: Score full point(s) if review item is met. Score zero (0) points if item is not met. Do not score partial points for any item. Explain all "N/A" and "No" (0 point) items in the comment section. Provide assistance/consultation as needed for CAPs and establish follow-up/verification timeline.

1) Add the points given in each section.
2) Add points given for all six (6) sections to determine total points given for the site.
3) Subtract all "N/A" items from 170 total possible points to determine the "adjusted" total possible points. If there are no "N/A" items, calculation of site score will be based on 170 points.
4) Divide the total points given by 170 or by the "adjusted" total. Multiply by 100 to calculate percentage rate.

Scoring Example:

Step 1: Add the points given in each section.

Step 2: Add points given for all six (6) sections.

Example: 31 (Access/Safety)
27 (Personnel)
25 (Office Management)
40 (Clinical Services)
13 (Preventive Services)
34 (Infection Control)
170 (POINTS GIVEN)

Step 3: Subtract "N/A" points from 170 total points possible.

170 (Total points possible)
- 5 (N/A points)
165 ("Adjusted" total points possible)

Step 4: Divide total points given by the "adjusted" points, then multiply by 100 to calculate percentage rate.

$$\frac{\text{Points given}}{\text{"Adjusted" total}} \quad \text{or} \quad \frac{140}{165} = 0.8485 \times 100 = \mathbf{85\%}$$

Criteria	I. Access/Safety Standards
A. Site is accessible and useable by individuals with physical disabilities.	**Sites must have the following safety accommodations for physically disabled persons:** **<u>Americans with Disabilities Act (ADA) Regulations</u>:** • Site must meet city, county, and state building structure and access ordinances for persons with physical disabilities. A site/facility includes the building structure, walkways, parking lots, and equipment. • All facilities designed, constructed; or altered by, on behalf of, or for the use of a public entity must be readily accessible and usable by individuals with disabilities, if the construction or alteration was begun after January 26, 1992.[1] • Any alteration to a place of public accommodation or a commercial facility, after January 26, 1992, must be made to ensure that, to the maximum extent feasible, the altered portions of the facility are readily accessible to and useable by individuals with disabilities, including individuals who use wheelchairs.[2] **I.A.1) Clearly marked (blue) curb or sign designating disabled-parking space near accessible primary entrance.** **<u>Parking</u>:** • Parking spaces for persons with physical disabilities are located in close proximity to accessible building entrances. • Each parking space reserved for persons with disabilities is identified by a permanently affixed reflectorized sign posted in a conspicuous place. • If the provider has no control over availability of accessible parking within lot or nearby street spaces for persons with disabilities, the provider must have a plan in place for making program services available to persons with physical disabilities. **I.A.2) Pedestrian ramps have a level landing at the top and bottom of the ramp.** **<u>Ramps</u>:** • A clear and level landing is at the top and bottom of all ramps and on each side of an exit door. • Any path of travel is considered a ramp if its slope is greater than a 1-foot rise in 20 feet of horizontal run. • Ramps must be a minimum of 36-inches wide. Some areas require wider ramps.

[1] Title 28, Code of Federal Regulations (CFR), section 35.151. The CFR is searchable at: https://www.ecfr.gov/search.
[2] 28 CFR section 36.402.

Criteria	I. Access/Safety Standards
	• All edges must be protected to keep anyone from slipping off. • All ramps that are 5 feet long shall have a level top and bottom landings. • Ramps must have handrails on both sides if length is longer than 6 feet. **I.A.3) Exit and exam room doorway openings allow for clear passage of a person in a wheelchair.** **<u>Exit Doors</u>:** • All entrances and exterior and interior exit doors, regardless of the occupant load shall be made accessible to persons with disabilities. • Exam room and exit doorways have a minimum opening of 32 inches with the door open at 90 degrees that will allow for passage of wheelchairs. • Door hardware = operable with a single effort without requiring ability to grasp hardware. • Effort to operate doors = a maximum pressure of 5 pounds at interior doors. • Door hardware height = 30” – 44” above floor. • Exit doors include all doors required for access, circulation and use of the building and facilities, such as primary entrances and passageway doors. • Furniture and other items do not obstruct exit doorways or interfere with door swing pathway. **I.A.4) Accessible passenger elevator or reasonable alternative for multi-level floor accommodation.** **<u>Elevators</u>:** • If there is no elevator, a freight elevator may be used to achieve program accessibility if it is upgraded for general passenger use and if passageways leading to and from the elevator are well-lit, neat, and clean. **I.A.5) Clear floor space for wheelchair in waiting area and exam room.** **<u>Clear Floor Space</u>:** • Clear space in waiting/exam areas is sufficient (at least 30-in. x 48-in.) to accommodate a single, stationary adult wheelchair and occupant. • A minimum clear space of 60-inch diameter or square area is needed to turn a wheelchair. **<u>Sanitary Facilities</u>:** **I.A.6) Wheelchair accessible restroom facilities.** • A wheelchair accessible restroom stall allows sufficient space for a wheelchair to enter and permits the door to close.

Criteria	I. Access/Safety Standards
	• Sufficient knee clearance space underneath the sink allows wheelchair users to safely use a lavatory sink for hand washing. • If wheelchair-accessible restrooms are not available within the office site, reasonable alternative accommodation are provided such as a wheelchair-accessible restroom located within the building. Other reasonable alternatives may include, but is not limited to, urinal, bedpan, or bedside commode in a private area. **IA.7) Wheelchair accessible handwashing facilities or reasonable alternative.** • Restroom and hand washing facilities are accessible to able-bodied and physically disabled persons. • If wheelchair-accessible handwashing facilities are not available within the office site, reasonable alternative accommodation are provided such as sanitizers and wheelchair-accessible restroom located within the building. **Note:** • A public entity may not deny the benefits of its program, activities, and services to individuals with disabilities because its facilities are inaccessible.[3] • Every feature need not be accessible, if a reasonable portion of the facilities and accommodations provided is accessible.[4] • Reasonable Portion and/or Reasonable Alternatives are acceptable to achieve program accessibility. • Reasonable Portion applies to multi-storied structures and provides exceptions to the regulations requiring accessibility to all portions of a facility/site. • Reasonable Alternatives are methods other than site structural changes to achieve program accessibility, such as acquisition or redesign of equipment, assignment of assistants/aides to beneficiaries, provision of services at alternate accessible sites, and/or other site-specific alternatives to provide services.[5] • Points shall not be deducted if Reasonable Portion or Reasonable Alternative is made available on site.

[3] 28 CFR sections 35.149 – 35.150.
[4] Title 24, California Code of Regulations (CCR), sections 2-419, California Administrative Code, the State Building Code. CCR is searchable at: https://govt.westlaw.com/calregs/Search/Index.
[5] Title II-5.2000 of the ADA Technical Assistance Manual, available at: https://www.ada.gov/taman2.html.

Criteria	I. Access/Safety Standards
	Specific measurements are provided strictly for "*reference only"* for the reviewer. Site reviewers are *NOT* expected to measure parking areas, pedestrian path of travel walkways and/or building structures on site.
B. Site environment is maintained in a clean and sanitary condition.	**I.B.1) All patient areas including floor/carpet, walls, and furniture are neat, clean, and well maintained.** • The physical appearance of floors/carpets, walls, furniture, patient areas, and restrooms are clean and well maintained. **I.B.2) Restrooms are clean and contain appropriate sanitary supplies.** • Appropriate sanitary supplies, such as toilet tissue, hand washing soap, cloth/paper towels or antiseptic towelettes are made available for restroom use. • Environmental safety includes the "housekeeping" or hygienic condition of the site. • Clean means unsoiled, neat, tidy, and uncluttered. • "Well maintained" means being in good repair or condition.
C. Site environment is safe for all patients, visitors and personnel.	**<u>Ordinances</u>:** • Sites must meet city, county, and state fire safety and prevention ordinances. • Reviewers should be aware of applicable city and county ordinances in the areas in which they conduct reviews. **There is evidence staff has received safety training and/or has safety information available on the following:** **I.C.1) Fire safety and prevention.** **I.C.2) Emergency non-medical procedures (e.g. site evacuation, workplace violence).** **<u>Emergency Action Plans</u>:** • Non-medical emergencies include incidents of fire, natural disaster (e.g. earthquakes), workplace violence, etc. • Specific information for handling fire emergencies and evacuation procedures is available on site to staff. Personnel know ***where to locate*** information on site, and ***how to use*** information.[6]

[6] 29 CFR section 1910.38

Criteria	I. Access/Safety Standards
	I.C.3) Lighting is adequate in all areas to ensure safety. **Illumination:** Lighting is adequate in-patient flow working and walking areas such as corridors, walkways, waiting and exam rooms, and restrooms to allow for a safe path of travel. **I.C.4) (CE) Exit doors and aisles are unobstructed and egress (escape) accessible.** **Access Aisle:** • Accessible pedestrian paths of travel (ramps, corridors, walkways, lobbies, elevators, etc.) between elements (seats, tables, displays, equipment, parking spaces, etc.) provide a clear circulation path. • The minimum clear passage needed for a single wheelchair is 36 inches along an accessible route but may be reduced to a minimum of 32 inches at a doorway. • Means of egress (escape routes) are maintained free of obstructions or impediments to full instant use of the path of travel in case of fire or other type of emergency. • Building escape routes provide an accessible, unobstructed path of travel for pedestrians and/or wheelchair users at all times when the site is occupied. • Cords (including taped cords) or other items are not placed on or across walkway areas. **I.C.5) Exit doors are clearly marked with "Exit" signs.** **Exits:** Exit doorways are unobstructed and clearly marked by a readily visible "Exit" sign.[7] **I.C.6) Clearly diagramed "Evacuation Routes" for emergencies are posted in a visible location at all elevators, stairs and exits.** **Evacuation Routes**: • Clearly diagramed "Evacuation Routes" for emergencies are posted in a visible location at all elevators, stairs and exits.[8] **I.C.7) Electrical cords and outlets are in good working condition.** **Electrical Safety:** • Electrical cords are in good working condition with no exposed wires, frayed or cracked areas. Cords are not affixed to structures, placed in or across walkways, extended through walls, floors, and ceiling, or under doors or floor coverings.

[7] 29 CFR 1910.37
[8] 29 CFR 1910.33-39, 19 CCR 3.09 (a) (1) (B).

Criteria	I. Access/Safety Standards
	• Extension cords are not used as a substitute for permanent wiring. • All electrical outlets have an intact wall faceplate. • Sufficient clearance is maintained around lights and heating units to prevent combustible ignition. **I.C.8) Fire Fighting Equipment in accessible location.** **Firefighting equipment:** **There is firefighting equipment that must be in accessible locations on site. At least one of the following types of fire safety equipment is on site:** • **Fire Extinguisher:** The employer shall provide portable fire extinguishers and shall mount, locate, and identify them so that they are readily accessible. Fire extinguishers are maintained in a fully charged and operable condition and kept in their designated places at all times except during use.[9] • Smoke Detector with intact batteries. • Automatic Sprinkler System With a 10-inch clearance between sprinkler heads and stored materials. **I.C.9) An employee alarm system.** **Employee Alarm System:** • Employers must install and maintain an operable employee alarm system that has a distinctive signal to warn employees of fire or other emergencies, unless employees can promptly see or smell a fire or other hazard in time to provide adequate warning to them.[10] OSHA: For those employers with 10 or fewer employees in a workplace, direct voice communication is an acceptable procedure for sounding the alarm provided all employees can hear the alarm. Such workplaces do not need a back-up system. **Note:** Specific measurements are provided strictly for "*reference only"* for the reviewer. Site reviewers are *NOT* expected to measure parking areas, pedestrian path of travel walkways and/or building structures on site.

[9] 29 CFR 1910.157
[10] 29 CFR 1910.37

Criteria	I. Access/Safety Standards
D. Emergency health care services are available and accessible 24 hours a day, 7 days a week. **RN/NP/CNM/LM/MD/PA**	**I.D. 1) Personnel are trained in procedures/action plan to be carried out in case of medical emergency on site.** **Site Specific Emergency Procedures:** • Staff can describe site-specific actions or procedures for handling medical emergencies until the individual is stable or under care of local emergency medical services (EMS). • There is a written procedure for providing immediate emergent medical care on site until the local EMS is on the scene. Although site proximity to emergency care facilities may be considered when evaluating medical emergency procedures, the key factor is the ability to provide immediate care to patients *on site* until the patient is stable or EMS has taken over care/treatment. • When the physician or non-physician medical practitioner (NPMP) is not on site, staff/MA may call 911, and CPR-certified staff may initiate CPR if needed. • Non-CPR-certified staff may only call 911 and stay with the patient until help arrives. **I.D.2) Emergency equipment is stored together in easily accessible location and is ready to be used.** **Emergency Medical Equipment:** During business hours providers are prepared to provide emergency services for management of emergency medical conditions that occur on site ***until*** the emergent situation is stabilized and/or treatment is initiated by the local 911 Emergency Medical Service (EMS) system. Minimum emergency equipment is available on site to: ○ Establish and maintain a patent/open airway. ○ Manage emergency medical conditions. Emergency equipment and medication, appropriate to patient population served, are available in an accessible location and ready for use. • An accessible location is one that is reachable by personnel standing on the floor, or other permanent working area, without locating/retrieving step stool, ladder or other assistive devices. • For emergency “Crash” cart/kit, contents are appropriately sealed and are within the expiration dates posted on label/seal. • Site personnel are appropriately trained and can demonstrate knowledge and correct use of all medical equipment they are expected to operate within their scope of work. https://www.aafp.org/afp/2007/0601/p1679.html

Criteria	I. Access/Safety Standards
	I.D. 3) Emergency phone number contacts are posted, updated annually and as changes occur. **<u>Emergency Phone Number list</u>:** Posted in an accessible and prominent location(s) and includes: ○ Local emergency response services (e.g., fire, police/sheriff, ambulance). ○ Emergency contacts (e.g., responsible managers, supervisors). ○ Appropriate State, County, City, and local agencies (e.g., local poison control number). The list should be dated, and telephone numbers updated annually and as changes occur. **Emergency medical equipment appropriate to practice/patient population is available on site:** **<u>I.D. 4) (CE) Airway management: oxygen delivery system, nasal cannula or mask, bulb syringe and Ambu bag</u>:** Without the ability to adequately maintain the patient's airway, all other interventions are futile. Minimum airway control equipment with various sizes of airway devices appropriate to patient population within the practice and examples of oxygen delivery systems include: ○ Wall oxygen delivery system ○ Portable oxygen tank ○ Portable oxygen concentrator (POC) All oxygen delivery systems must be able to be regulated up to 6 liters of oxygen per minute, maintained for a minimum of 15 minutes. This flow rate establishes a minimum total oxygen delivery capacity of 90 liters for these devices:[11] ○ Nasal cannula or mask ○ Bulb syringe ○ Ambu bag as appropriate to patient population served. Mask should be replaced when they no longer make a solid seal.

[11] See the Food and Drug Administration (FDA) guidelines for oxygen generators and oxygen equipment for emergency use, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/review-guidelines-oxygen-generators-and-oxygen-equipment-emergency-use

	○ Portable oxygen tanks are maintained at least ¾ full. There is a method/system in place for oxygen tank replacement. If oxygen tanks are less than ¾ full at time of site visit, site has a back-up method for supplying oxygen if needed ***and*** a scheduled plan for tank replacement. ○ Oxygen tubing does not need be connected to oxygen tank, but must be kept in close proximity to tank. Oropharyngeal airways are no longer required. **I.D.5) (CE) Emergency medicine for anaphylactic reaction management, opioid overdose, chest pain, asthma, and hypoglycemia:** Severe allergic reaction can cause urticaria (hives), hypotension, bronchospasm, wheezing, and pulmonary edema. Per the American Academy of Family Practice (AAFP), the minimum equipment to manage emergency anaphylactic reaction, asthma exacerbation, chest pain, opioid overdose, and hypoglycemia, based on the patient population served, shall include: ○ Epinephrine 1mg/mL (injectable) ○ Diphenhydramine 25 mg (oral) or 50 mg/ml (injectable) ○ Naloxone[12] ○ Chewable aspirin 81 mg[13] ○ Nitroglycerin spray/tablet[14] ○ Bronchodilator medication (solution for nebulizer or metered dose inhaler) ○ Glucose (any type of glucose containing at least 15 grams) ○ Appropriate sizes of ESIP needles/syringes[15] and alcohol wipes • The typical adult strength to address cardiac emergencies is 325 mg (four doses of 81 mg chewable aspirin or one dose of 325 non-enteric coated aspirin). • If the site is seeing adults, the reviewer shall assess whether the appropriate number of chewable aspirin tablets of 81 mg is available (at least four tablets). **I.D.6) Medication dosage chart for all medications included with emergency equipment (or other method for determining dosage) is kept with emergency medications.** • There is a current medication administration reference (e.g. medication dosage chart) available for readily identifying the correct medication dosages (e.g. adult, pediatric, infant, etc.). • Package inserts are not acceptable as dosage charts. • All emergency medications in the emergency kit/ crash cart must have dosage charts. Score should be either a **Yes or No only** **There is a process in place on site to:**

[12] In 2018, the U.S. Surgeon General issued an advisory emphasizing the importance of health care professionals having naloxone (an opioid antagonist) on hand and being trained in how to use it. The U.S. Surgeon General's advisory is available at: https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html. Also see the FDA's approval of Narcan to reverse opioid overdose: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/narcan-naloxone-nasal-spray-approved-reverse-opioid-overdose, and articles regarding overdose preparedness for ambulatory clinics, available at: https://www.aafp.org/fpm/2021/0100/p17.html and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/.

[13] See the American Heart Association's article on Aspirin and Heart Disease, available at: https://www.heart.org/en/health-topics/heart-attack/treatment-of-a-heart-attack/aspirin-and-heart-disease.

[14] Pediatric offices only serving patients under 18 years old are not required to keep Nitroglycerin in their emergency kit. According to the FDA, "The safety and effectiveness of nitroglycerin in pediatric patients (under 18 years old) have not been established." Also see page 8 of an article on Nitrostat, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021134s007lbl.pdf.

[15] If the emergency kit or "crash cart" has only non-safety needles/syringes, score that deficiency in Section VI., Infection Control, criteria B.2. See Infection Control Standards.

Criteria	I. Access/Safety Standards
	I.D.7) Document checking of emergency equipment/supplies for expiration and operating status at least monthly. Documented evidence that emergency medication and equipment is checked at least monthly may include a log, checklist or other appropriate method(s). **I.D.8) Replace/re-stock emergency medication, equipment, and supplies immediately after use.** A receipt or documentation showing medication is ordered is acceptable for any medication shortage. **Note:** An "emergency medical condition" is a medical condition that manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: 1) placing the health of the individual (or unborn child of a pregnant woman) in serious jeopardy 2) serious impairment to bodily functions 3) serious dysfunction of any bodily organ or part "Emergency services" means those services required for alleviation of severe pain, or immediate diagnosis and treatment of unforeseen medical conditions, which, if not immediately diagnosed and treated, would lead to disability or death.
E. Medical and lab equipment used for patient care is properly maintained. **RN/NP/CNM/LM/MD/PA**	**I.E.1) Medical equipment is clean.** **Medical and Laboratory Equipment:** All equipment used to measure or assess patient health status/condition is clean. **I.E.2) Written documentation demonstrates the appropriate maintenance of all medical equipment according to equipment manufacturer's guidelines.** **Documentation:** • There is documented evidence that standard operating procedures have been followed for routine inspection/maintenance, calibration, repair of failure or malfunction, and testing and cleaning of all specialized equipment. • Appropriate written records include calibration or other written logs, work orders, service receipts, dated inspection sticker, etc.

Criteria	I. Access/Safety Standards
	• All equipment used to measure or assess patient health status/condition is functioning properly. All specialized equipment (e.g., ultrasonography equipment, electrocardiogram (EKG) machine, defibrillator, audiometer, hemoglobin meter, glucometer, scales, etc.) are adequately maintained according to the specified manufacturer's guidelines for the equipment or is serviced annually by a qualified technician. • Blood pressure cuffs, monitors, and other related equipment need not be calibrated unless required by the manufacturer. Manufacturer guidelines must be available on site, indicating that it is not necessary to calibrate the equipment. **Note:** The term monitor includes, but not limited to, glucometers, EKG, BP monitors, hemocues, and audiometers.

Criteria	II. Personnel Standards		
A.1. Professional health care personnel have current California licenses and certifications.	**Medical Professional**	**License/Certification**	**Issuing Agency**
	Certified Nurse Midwife (CNM)	RN License & Nurse-Midwife Certificate. Drug Enforcement Agency (DEA) Registration, *if appropriate*	CA Board of Registered Nursing DEA
	Certified Radiological Technologist (CRT)	CRT Certificate.	California Department of Public Health (CDPH), Radiologic Health Branch
	Doctor of Osteopathy (DO)	Physician's & Surgeon's Certificate DEA Registration	Osteopathic Medical Board of CA DEA
	Licensed Midwife (LM)	Licensed Midwife Certificate. Drug Enforcement Agency (DEA) Registration, *if appropriate*	Medical Board of CA DEA
	Licensed Vocational Nurse (LVN):	LVN License	CA Board of Vocational Nursing and Psychiatric Technicians
	Nurse Practitioner (NP)	RN License w/NP Certification & Furnishing Number DEA Registration, *if appropriate*	CA Board of Registered Nursing DEA
	Pharmacist (Pharm. D)	Pharmacist License	CA State Board of Pharmacy
	Physician/Surgeon (MD)	Physician's & Surgeon's Certificate DEA Registration	Medical Board of CA DEA
	Physicians' Assistant/ Associate (PA)	PA License DEA Registration, *if appropriate*	Physician Assistant Examining Committee/Medical Board of CA DEA
	Radiological Technician	Limited Permit	CDPH, Radiologic Health Branch

<table>
<tr><th>Criteria</th><th colspan="3">II. Personnel Standards</th></tr>
<tr><td></td><td>Registered Dietitian (RD)</td><td>RD Registration Card</td><td>Commission on Dietetic Registration</td></tr>
<tr><td></td><td>Registered Nurse (RN)</td><td>RN License</td><td>CA Board of Registered Nursing</td></tr>
<tr><td></td><td colspan="3">II.A.1) All required Professional Licenses and Certifications, issued from the appropriate licensing/certification agency, are current.
<u>Note</u>: All medical professional licenses and certifications must be current and issued from the appropriate agency for practice in California, and available on site. Although sites with centralized personnel departments are not required to keep documents or copies on site, copies and/or lists of currently certified or credentialed personnel must be readily available when requested by reviewers.</td></tr>
<tr><td rowspan="2">A.2. All required professional licenses and certifications, issued from the appropriate licensing/certification agency, are current.</td><td colspan="2"><u>Note</u>:
Effective June 27, 2010, MDs (does not apply to Osteopaths) shall provide notification to each patient that states the MD(s) on site is licensed and regulated by the Board, and includes the following:[16]

NOTICE
Medical doctors are licensed and regulated by the Medical Board of California
(800) 633-2322
www.mbc.ca.gov.</td><td><u>Note</u>:
Effective August 11, 2011, PAs shall provide notification to each patient that states the PA(s) is licensed and regulated by the Physician Assistant Board , and includes the following:[17]

NOTIFICATION TO CONSUMERS
Physician Assistants are licensed and regulated by the Physician Assistant Board
(916) 561-8780
www.pab.ca.gov</td></tr>
<tr><td colspan="3">II.A.2) Notification is provided to each member that the MD(s) is licensed and regulated by the Medical Board, and that the Physician Assistant(s) is licensed and regulated by the Physician Assistant Board.

The notice to consumers above shall be provided by one of the following methods:</td></tr>
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[16] 16 CCR 1355.4, as mandated by Business and Professions Code (BPC) section 138.
[17] 16 CCR 1399.547, as mandated by BPC section 138.

Criteria	II. Personnel Standards
	○ Prominently posted sign in an area visible to patients in at least 48-pt Arial font. ○ A written statement signed and dated by the patient (or patient's representative) and kept in the medical record, stating the patient understands that the MD is licensed and licensed and regulated by the board (for PA's, that the PA is licensed and regulated by the PA Board). ○ A statement on letterhead, discharge instructions or other document given to the patient (or patient's representative), where the notification is placed immediately above the signature line for the patient in at least 14-pt font.
B. Health care personnel are properly identified.	**II.B.1) Health care personnel wear identification badges/tags printed with name and title.** • Health care personnel shall disclose, while working, their name and title on a name tag at least 18-point type. • It is acceptable for health care personnel in a practice or an office, whose license is prominently displayed, to opt not to wear a nametag. **<u>Note</u>:** • In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title "nurse" in reference themselves, in any capacity, except for an individual who is a registered nurse, or a licensed vocational nurse. • "Health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under Business and Professions Code (Sections 680-681). If a health care practitioner or licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, the employing entity or agency shall have the discretion to make an exception from the nametag requirement for the individual safety or therapeutic concerns.
C. Site personnel are qualified and trained for assigned responsibilities. **RN/NP/CNM/LM/MD/PA**	**<u>Unlicensed Personnel</u>:** Medical assistants (MAs) are unlicensed health personnel, at least 18 years of age, who perform basic administrative, clerical, and non-invasive routine technical supportive services under the supervision of a licensed physician, surgeon, or podiatrist in a medical office or clinic setting. • "Supervision" means the licensed physician must be physically present in the treatment facility during the performance of authorized procedures by the MA.

Criteria	II. Personnel Standards
	• Per Business and Professions Code Section 2069 (a) (1), a supervising physician and surgeon at a "community clinic" licensed under Health and Safety Code section 1204(a) may, at their discretion, in consultation with the nurse practitioner, nurse midwife, or physician assistant provide written instructions to be followed by a medical assistant in the performance of tasks or supportive services. • The written instructions may provide that the supervisory function for the medical assistant in performing these tasks or supportive services may be delegated to the nurse practitioner, nurse midwife, or physician assistant and that those tasks may be performed when the supervising physician and surgeon is not on site. **II.C.1) Documentation of education/training for non-licensed medical personnel is maintained on site.** • Training may be administered under a licensed physician; or under an RN, LVN, PA, or other qualified medical assistant acting under the direction of a licensed physician. The supervising physician is responsible for determining the training content and ascertaining proficiency of the MA. Training documentation maintained on site for the MA must include the following: • Diploma or certification from an accredited training program/school, or • Letter/statement from the current supervising physician that certifies in writing: date, location, content, and duration of training, demonstrated proficiency to perform current assigned scope of work, and signature. **II.C.2) (CE) Only qualified/trained personnel retrieve, prepare or administer medications.** Medication administration by an MA means the direct application of pre-measured medication orally, sublingually, topically, vaginally or rectally; or by providing a single dose to a patient for immediate self-administration by inhalation or by simple injection. • **All medications including vaccines must be verified with (shown to) a licensed person prior to administration.** • Unlicensed staff (e.g. MAs) have evidence of appropriate training and supervision in all medication administration methods performed within their scope of work. • To administer medications by subcutaneous or intramuscular injection, or to perform intradermal skin tests or venipunctures for withdrawing blood, an MA must have completed at least the minimum number of training-hours established in CCR, Title 16, Section 1366.1.

Criteria	II. Personnel Standards
	<u>Note</u>: • **MAs cannot administer anesthetics, including local anesthetic agents (such as Rocephin hydrated with Xylocaine).** [18] • MAs may not place an intravenous needle, start or disconnect the intravenous infusion tube, administer medications or injections into an intravenous line, or administer anesthesia. • The supervising physician must specifically authorize all medications administered by an MA. "Authorization" means a specific written or standing order prepared by the supervising physician. **II.C.3) Site has a procedure in place for confirming correct patient, correct medication/vaccine, correct dosage, and correct route prior to administration.** • To help reduce the risk of medication errors, staff shall follow procedures for confirming the correct patient, correct medication/vaccine, correct dosage, and correct route prior to administration. **II.C.4) Only qualified/trained personnel operate medical equipment.** **<u>Medical Equipment</u>:** • Provider and/or staff can demonstrate appropriate operation of medical equipment used in their scope of work. Not all staff is required to be proficient in use of all equipment but at any given time, a staff must be prepared to operate equipment that is not routinely needed by every patient such as patient lifts and accessible scales. Health care personnel at the site must demonstrate that they can turn on the oxygen tank and tell when an oxygen tank needs to be replaced and/or refilled. **<u>Note</u>:** • Personnel on site must be qualified for their responsibilities and adequately trained for their scope of work. • Site staff should have a general understanding of the systems/processes in place, appropriate supervision, and knowledge of the available sources of information on site.

[18] 16 CCR 1366.3(a) (1), also see information from the Medical Board of California on Medical Assistants, available at: https://www.mbc.ca.gov/Licensing/Physicians-and-Surgeons/Practice-Information/Medical-Assistants.aspx. https://www.mbc.ca.gov/FAQs/?cat=Licensees&topic=Medical%20Assistants

Criteria	II. Personnel Standards
	• Family members and personal care assistants, whether paid or unpaid, are not "unlicensed personnel" or otherwise captured within the scope of this tool.
D. Scope of practice for non-physician medical practitioners (NPMP) is clearly defined. 🗣 🗁 **RN/NP/CNM/LM/MD/PA**	**II.D.1) Standardized Procedures provided for NPs and/or CNMs.** • The scope of practice for NPs and CNMs is clearly defined including the delegation of the supervision of MAs when supervising physician is off premises. • Documents may be utilized to determine and/or clarify practice procedures and supervisory processes on site. • Reviewers are expected to verify that NP and/or CNM standardized procedures, and PA Practice Agreement and Supervision Physician's Responsibility documentation are present on site. • Reviewers are ***not*** expected to make in-depth evaluation of "appropriateness" of the NPMP's scope of practice. **NPs:** • NPs are prepared through education and experience to provide primary care and to perform advanced procedures. • The extent of required supervision must be specified in the Standardized Procedures. • Standardized procedures legally define the expanded scope of nursing practice that overlaps the practice of medicine. • Standardized Procedures should identify the furnishing of drugs or devices, extent of physician or surgeon supervision, method of periodic review of competence, including peer review, and review of provisions in the Standardized Procedures. **CNM:** • The certificate to practice nurse-midwifery authorizes the holder, under supervision of a licensed physician or surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family planning care for the mother, and immediate care for the newborn. • The supervising and back-up physician or surgeon for the CNM must be credentialed to perform obstetrical care in the same delivering facility in which the CNM has delivery privileges.

Criteria	II. Personnel Standards
	Note: CNMs and NPs operate under written Standardized Procedures that are collaboratively developed and approved by the supervising physician, the NP and administration within the organized health care facility/system in which standardized procedures will be used. **II.D.2) A Practice Agreement defines the scope of services provided by PAs and Supervisory Guidelines define the method of supervision by the Supervising Physician.** **PA:** • Practice Agreement: a) Defines specific procedures identified in practice protocols or specifically authorized by the supervising physician, and must be dated and signed by physician and PA. b) The delegation of the supervision of MAs when supervising physician is off premises. c) An original or copy must be readily accessible at all practice sites in which the PA works. d) Failure to maintain a Practice Agreement is a violation of the PA Regulations and is grounds for disciplinary action by the Medical Board of California against a physician assistant's licensure. • Supervising Physician's Responsibility for Supervision of PAs' Practice Agreement: Defines supervision responsibilities and methods required by Title 16, section 1399.545 of the Physician Assistant Regulations, and is signed by the physician. The following procedures must be identified: ○ Emergency transport of patients and back-up procedures (e.g., can call 911, name of hospital to transport patient included in Practice Agreement) for when the supervising physician is not on the premises. **Note:** • A Delegation of Services Agreement (DSA) in effect prior to January 1, 2020, shall be updated to meet the current requirements.[19] • DSAs that still reflect components that are no longer required by BPC section 3502.3 should be enforced since the DSA is the currently established agreement between the PA and the supervising physician. • The reviewer should assess the site's process for compliance with the DSA.

[19] BPC 3502.3

Criteria	II. Personnel Standards
	• Any deficiency shall result in a CAP requesting the site to adhere to the DSA components or establish a new Practice Agreement. **II.D.3) Standardized Procedures, Practice Agreements, and Supervisory Guidelines are revised, updated, and signed by the supervising physician and NPMP when changes in scope of services occur.** • Standardized Procedures, Practice Agreements shall undergo periodic review, with signed, dated revisions completed at each change in scope of work by supervising physician. • Frequency of the review to identify changes in scope of service shall be specified in writing. **II.D.4) Each NPMP that prescribes controlled substances has a valid DEA Registration Number.** **DEA:** Each NP, CNM, and PA that prescribes controlled substances is required to have a valid DEA Registration Number.

E. Non-physician medical practitioners (NPMP) are supervised according to established standards.
RN/NP/CNM/LM/MD/PA
	The designated supervising physician(s) on site:
	
	II.E.1) Ratio to number of NPMPs does not exceed established ratios in any combination.
	NPMPs:
	• The supervising physician holds ultimate responsibility for the practice of each supervised NPMP.
	• The maximum number of NPMPs who may be supervised by a single primary care physician (PCP) is limited to the following at any given time/shift in any of their locations:[20]
	  ○ 4 NPs with furnishing license (there is no limit to the number of NPs the physician may supervise if the NP does not hold a furnishing license);
	  ○ 4 CNMs; and
	  ○ 4 PAs.

[20] BPC 3516(b), Welfare and Institutions Code (WIC) section 14132.966

Criteria	II. Personnel Standards
	This ratio is based on each physician, not the number of offices. A PCP, an organized outpatient clinic, or a hospital outpatient department cannot utilize more NPMPs than can be supervised within these stated limits. Physician Assistant Board (PAB) is at https://www.pab.ca.gov/ or the PAB office at 916-561-8780. **II.E.2) The designated supervising or back-up physician is available in person or by electronic communication at all times when a NPMP is caring for patients.** **Supervising Physician**: • "Supervision" means that a licensed physician and surgeon oversee the activities of, and accept responsibility for, the medical services rendered by a PA. • Supervising or back-up physician is available in person or by electronic communication at all times when a NPMP is caring for patients. **II.E.3) Evidence of NPMP supervision.** **Evidence of NPMP Supervision:** • Standardized Procedures for NP or CNM should identify the furnishing of drugs or devices, extent of physician or surgeon supervision, method of periodic review of competence, including peer review, and review of provisions in the Standardized Procedures.[21] • Standardized Procedures shall undergo periodic review, with signed, dated revisions completed at each change in scope of work. • Evidence of supervision of NPMP(s) are verifiable through on-site observation of supervisory processes, documentation, or supervisor/NPMP's knowledge of the process.
F. Site personnel receive safety training. 🗁 **RN/NP/CNM/LM/MD/PA**	**II.F. There is evidence that site staff has received training on the following:** **1) Infection Control/Universal Precautions (annually)** **2) Bloodborne Pathogens Exposure Prevention (annually)** **3) Biohazardous Waste Handling (annually)** Training occurs ***prior to*** initial exposure to potentially infectious and/or biohazardous materials. Review and re-training sessions occur ***at least annually***. Training content is appropriate (language, educational level, etc.) to personnel on site.

[21] BPC 2834

Criteria	II. Personnel Standards
	Training *minimally* includes the following: o Universal/standard precautions o Use of personal protective equipment o Accessible copy of Bloodborne Pathogens Standard o Work practice controls/exposure prevention o Modes of transmitting bloodborne pathogens o Epidemiology/symptoms of HBV and HIV o Recognition of activities with exposure element o Handling and labeling of biohazardous waste(s) o Hepatitis B vaccination protocol and requirements o Explanation of emergency procedures o Post exposure reporting/evaluation/follow-up procedures o Decontamination of equipment/work areas o Site's written bloodborne pathogen exposure plan o Opportunity for discussion/questions Personnel must know ***where to locate*** information/resources on site about infection control, the Bloodborne Pathogens Exposure Plan, and ***how to use*** the information. Evidence of training must be verifiable. Evidence of training may include: o Informal in-services o New staff orientation o External training courses o Educational curriculum o Participation lists, etc. Training documentation must contain: 1) Employee's name 2) Job titles 3) Training date(s) 4) Type of training 5) Contents of training session 6) Names/qualifications of trainers Records must be kept for three (3) years.

Criteria	II. Personnel Standards
	Note: Site personnel treat all blood and other potentially infectious materials (OPIM) as if these *are* infectious. Site personnel who are reasonably anticipated to have eye, skin, mucous membranes and potential exposure to blood and/or OPIM receive training as required by the Bloodborne Pathogens Standard.[22]
G. Site personnel receive training on member rights. **RN/NP/CNM/LM/MD/PA**	**II.G. There is evidence that site staff has received information and/or training on the following:** **II.G.1) Patient Confidentiality** • Site personnel have received information and/or training about patient confidentiality and must be prepared to provide information on how patient confidentiality is protected at the site. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written patient confidentiality information on site and explain how to use information. **II.G.2) Informed Consent, including Human Sterilization** • Site personnel have received information and/or training on informed consent, including human sterilization. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written informed consent, including human sterilization information on site and explain how to use information. **II.G.3) Prior Authorization Requests** • Site personnel have received information and/or training on prior authorization requests.

[22] 8 CCR 5193

Criteria	II. Personnel Standards
	• Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written prior authorization requests information on site and explain how to use information. **II.G.4) II.F.4) Grievance/Complaint Procedure** • Site personnel have received information and/or training on grievance/complaint procedure. Staff must be prepared to provide information to patient when requested. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written grievance/complaint procedures information on site and explain how to use information. **II.G.5) Child/Elder/Domestic Violence Abuse Reporting**: Site personnel have specific knowledge of local reporting requirements, agencies, and procedures, and know *where to locat*e information on site and *how to use* information. **Note:** • Health practitioners (e.g., physicians, surgeons, licensed nurses, licensed social workers, paramedics) in a health facility, (e.g., clinic, physician's office, public health clinic) are legally mandated reporters of known or reasonably suspected cases of child abuse, elder abuse and domestic violence. • Legally mandated reporters must make telephone and written reports according to timeliness standards established by the designated local law enforcement agencies in each county. "Reasonably suspected" means having objectively reasonable suspicion based upon facts that could cause a reasonable person in a like position, drawing when appropriate on his or her training and experience, to suspect abuse (CA Penal Code 11164). • Failure to report by legally mandated reporters can result in criminal or civil prosecutions, punishable by monetary fines and/or county jail confinement.

Criteria	II. Personnel Standards
	Any person entering employment, which makes him/her a mandated reporter, must sign a statement, provided and retained by the employer, that the employee has knowledge of the Child Abuse reporting law and will comply with its provision.[23] **II.G.6) Sensitive Services/Minors' Rights** • Site personnel have received information and/or training on sensitive services/minors' rights. Sensitive Services include family planning, pregnancy, sexually transmitted infections, etc. • PCP sites must have basic information on sensitive services that are appropriate to their practice office and be prepared to provide information to patients when needed. • Minor's Rights: California Family Code provides that a minor may, without parental consent, receive a number of sensitive services including outpatient mental health treatment and counseling for children 12 years and older. **II.G.7) Health Plan Referral Process/Procedures/Resources** • Site personnel have received information and/or training on health plan referral process/procedures/resources. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written health plan referral process/procedures/resources information on site and explain how to use information. **II.G.8) Cultural and Linguistic Training** • Site personnel have received information and/or training on cultural and linguistic appropriate services. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written cultural and linguistic information on site and explain how to use information. Cultural and Linguistic

[23] Penal Code section 11166.5

Criteria	II. Personnel Standards
	Training- Culturally and Linguistically Appropriate Services (CLAS) mandates are Federal requirements for all recipients of Federal funds.[24] **II.G.9) Disability Rights and Provider Obligations** • Site personnel have received information and/or training on patient rights and provider obligations under the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973, and/or Section 1557 of the Affordable Care Act • Training content should include information about physical access, reasonable accommodations, policy modifications, and effective communication in healthcare settings. **https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/504.pdf** **https://www.hhs.gov/sites/default/files/section-1557-final-rule-faqs.pdf** **https://www.hhs.gov/sites/default/files/1557-fs-lep-508.pdf**

[24] See the National Standards on CLAS, available at: https://www.health.pa.gov/topics/Documents/Health%20Equity/CLAS%20Standards%20FactSheet.pdf.

Criteria	III. Office Management Standards
A. Physician coverage is available 24 hours a day, 7 days a week.	**III.A.1) Clinic office hours are posted or readily available upon request.** Current clinic office hours are posted within the office or readily available upon request. **III.A.2) Provider office hour schedules are available to staff.** **III.A.3) Arrangement/schedule for after-hours, on-call, supervisory back-up physician coverage is available to site staff and members after-hours.** Current site-specific resource information is available to site personnel and members about physician office hour schedule(s), local and/or Plan-specific systems for after-hours urgent care, emergent physician coverage available 24 hours a day, 7 days per week, and system for providing follow-up care. **III.A.4) Contact information for off-site physician(s) is available at all times during office hours.** When a physician is not on site during regular office hours, personnel are able to contact the physician (or covering physician) at all times by telephone, cell phone, pager, etc. **III.A.5) Routine, urgent and after-hours emergency care instructions/telephone information is made available to patients.** **Note:** One objective of effective clinic office management is to support the provision of appropriate, coordinated health care services. The review of clinic office management is to evaluate if effective systems are in place and whether site personnel appropriately follow established site-specific procedures.
B. There are sufficient health care personnel to provide timely, appropriate health Care services. **RN/NP/CNM/LM/MD/PA**	**III.B.1) Appropriate personnel handle emergent, urgent, and medical advice telephone calls.** • In addition to the physician, only appropriately licensed medical personnel such as a CNM, LM, NP, RN, or PA handles emergency, urgent, and medical advice/triage telephone calls.

Criteria	III. Office Management Standards
	• The California Board of Vocational Nursing and Psychiatric Technician Examiners has determined that the Licensed Vocational Nurse Practice Act does not permit the LVN to perform triage independently.[25] • The LVN may perform that part of the triage process that includes observation and data collection relative to basic physical assessment. • The LVN may not perform that part of the triage process that includes independent evaluation, interpretation of data, and determination of treatment priorities and levels of care. • Unlicensed personnel, such as medical assistants, may provide patient information or instructions only as authorized by the physician.[26] **Note:** Telephone triage is the system for managing telephone calls during ***and*** after office hours. **III.B.2) Telephone answering machine, voice mail system, or answering service is used whenever office staff does not directly answer phone calls.** • Telephone answering machine, voice mail system, or answering service is used whenever office staff does not directly answer phone calls. **III.B.3) Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated.** • Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated.
C. Health care services are readily available. **RN/NP/CNM/LM/MD/PA**	**III.C.1) Appointments are scheduled according to patients stated clinical needs within the timeliness standards established for Plan members.** **Note:** Medi-Cal Managed Care Health Plans *require* the following timeliness standards for access to appointments: ○ Urgent Care: 48 hours ○ Access to the first Prenatal Visit: 10 business days ○ Non-urgent (Routine) Care: 10 business days

[26] 16 CCR 1366(b)

Criteria	III. Office Management Standards
	III.C.2) Patients are notified of scheduled routine and/or preventive screening appointments. • The process established on site provides timely access to appointments for routine care, urgent care, prenatal care, pediatric periodic health assessments/immunizations, adult initial health assessments, specialty care, and emergency care. • Systems, practices, and procedures used for making services readily available to patients will vary from site to site. **III.C.3) There is a process in place verifying follow-up on missed and canceled appointments.** • An organized system must be evident (in use) for scheduling appointments appropriately, notifying, and reminding members of scheduled appointments, and following up on missed or canceled appointments. • Missed and/or canceled appointments and contact attempts must be documented in the patient's medical record.
D. There is 24-hour access to interpreter services for non- or limited-English proficient (LEP) members.	**III.D.1) Interpreter services are made available in identified threshold languages specified for location of site.** • Sites must provide 24-hour interpreter services for all members either through telephone language services or interpreters on site. **III.D.2) Persons providing language interpreter services, including sign language on site, are trained in medical interpretation.** • Site personnel used as interpreters have been assessed for their medical interpretation performance skills/capabilities. • Reviewer should ask for a written policy which includes the languages spoken by bilingual providers and staff. **Note:** https://www.lep.gov; 22 CCR 51309.5 • If bilingual staff are asked to interpret or translate, they should be qualified to do so. Assessment of ability, training on interpreter ethics and standards, and clear policies that delineate appropriate use of bilingual staff, staff or contract interpreters and translators, will help ensure quality and effective use of resources.

Criteria	III. Office Management Standards
	• Those utilizing the services of interpreters and translators should request information about certification, assessments taken, qualifications, experience, and training. Quality of interpretation should be a focus of concern for all recipients. • Family or friends should not be used as interpreters, unless specifically requested by the member's circumstances. Minors, under 18 years old, accompanying members shall not be used as interpreters. • The Affordable Care Act of 2010, Section 1557: prohibits from using low-quality video remote interpreting services or relying on unqualified staff, translators when providing language assistance services. • A request for or refusal of language/interpreter services must be documented in the member's medical record. Sign language interpreter services may be utilized for medically necessary health care services and related services such as: ○ Obtaining medical history and health assessments ○ Obtaining informed consents and permission for treatments ○ Medical procedures ○ Providing instructions regarding medications ○ Explaining diagnoses ○ Treatment and prognoses of an illness ○ Providing mental health assessment ○ Therapy or counseling
E. Procedures for timely referral/ consultative services are established on site. 🗁 **RN/NP/CNM/LM/MD/PA**	**Office practice procedures allow timely provision and tracking of:** **III.E.1)Processing internal and external referrals, consultant reports, and diagnostic test results.** • An organized, timely referral system is evident for making and tracking referrals, reviewing reports, providing/scheduling follow-up care and filing reports in medical records. • Referral informational resources are readily available for use by site personnel. • Site staff can demonstrate (e.g., "walk through") the office referral process from beginning to end Systems, practices, and procedures used for handling referrals will vary from site-to-site.

Criteria	III. Office Management Standards
	III.E.2 (CE) Physician Review and follow-up of referral/consultation reports and diagnostic test results. • There is a documented process of the practitioner review of diagnostic tests/consultations and subsequent outreach to follow-up with the patient to communicate results and provide next steps. • Practitioner review is evidenced by date and signature/initials on the report of the reviewing practitioner.
F. Member grievance/ complaint processes are established on site.	**III.F.1) Phone number(s) for filing grievances/complaints are located on site.** • At least one telephone number for filing grievances is posted on site or is readily available upon request. **III.F.2) Complaint forms and a copy of the grievance procedure are available on site.** • Complaint forms and a copy of the grievance procedure are readily available on site and can be provided to members promptly upon request. • Includes The Department of Managed Health Care Help Center 1-888-466-2219 and Ombudsman 1-888-452-8609. **Note:** A "grievance" is defined as any written or oral expression of dissatisfaction and shall include any complaint, dispute, and request for reconsideration or appeal made by an enrollee or their representative to a Plan or entity with delegated authority to resolve grievances on behalf of the Plan.
G. Medical records are available for the practitioner at each scheduled patient encounter.	**III.G.1) Medical records are readily retrievable for scheduled patient encounters.** • The process/system established on site provides for the availability of medical records (paper and electronic), including outpatient, inpatient, referral services, and significant telephone consultations for patient encounters.

Criteria	III. Office Management Standards
	III.G.2) Medical documents are filed in a timely manner to ensure availability for patient encounters. • Medical records are filed in a timely manner that allows for ease of accessibility within the facility or in an appropriate health record storage facility if stored off-premises.[27]
H. Confidentiality of personal medical information is protected according to State and federal guidelines. **RN/NP/CNM/LM/MD/PA**	**III.H.1) Exam rooms and dressing areas safeguard patients' right to privacy.** **Privacy:** • Patients have the right to privacy for dressing/undressing, physical examination, and medical consultation. • Practices are in place to safeguard patient privacy. • Because dressing areas and examination room configurations vary greatly, reviewers will make site-specific determinations. **III.H.2) Procedures are followed to maintain the confidentiality of personal patient information.** **Confidentiality:** • Personnel follows site policy/procedures for maintaining confidentiality of individual patient information. • Individual patient conditions or information is not discussed in front of other patients or visitors, displayed or left unattended in reception and/or patient flow areas (this includes unattended electronic devices, patient registration sign-in sheets with more than one unique patient identifier). • There must be a confidentiality agreement between the provider and the cleaning service agency/persons if the medical records are kept in an open space and/or are unsecured. **Electronic Records:** • Electronic record-keeping system procedures have been established to ensure patient confidentiality, prevent unauthorized access, authenticate electronic signatures, and maintain upkeep of computer systems.

[27] 22 CCR 75055

Criteria	III. Office Management Standards
	• Security protection includes an off-site backup storage system, an image mechanism with the ability to copy documents, a mechanism to ensure that recorded input is unalterable, and file recovery procedures. • Confidentiality protection may also include use of encryption, detailed user access controls, transaction logs, and blinded files. **III.H. 3) Medical record release procedures are compliant with State and federal guidelines.** **<u>Record Release</u>:** • Medical records are not released without written, signed consent from the patient or patient's representative, identifying the specific medical information to be released. • The release terms, such as to whom records are released and for what purposes, and the expiration date of the consent to medical record release should also be described. • This does not prevent release of statistical or summary data, or exchange of individual identifiable medical information between individuals or institutions providing care, fiscal intermediaries, research entities and State or local official agencies.[28] **III.H.4) Storage and transmittal of medical records preserves confidentiality and security.** **<u>Storage and transmittal:</u>** • Health care services rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, shall confidentially and securely keep and maintain records of each service rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, the beneficiary or person to whom rendered, the date the service was rendered, and any additional information as the department may by regulation require. • FAX cover sheet shall have confidentiality statement. **III.H.5) Medical records are retained for a minimum of 10 years.** **<u>Record Retention:</u>** • Records required to be kept and maintained under this section (including minors under 18 years old) shall be retained by the provider for a period of 10 years from the final date of the contract

[28] 45 CFR 164.524

Criteria	III. Office Management Standards
	period between the plan and the provider, from the date of completion of any audit, or from the date the service was rendered, whichever is later, in accordance with 42 CFR 438.3(u).[29]

[29] WIC 14124.1

Criteria	IV. Clinical Services - Pharmaceutical Standards
A. Drugs and medication supplies are maintained secured to prevent unauthorized access.	**Deficiencies:** All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, disposition, etc.) must be addressed in a corrective action plan. **IV.A.1) Drugs are stored in specifically designated cupboards, cabinets, closets or drawers.** **Security**: • All drugs for dispensing are stored in an area that is secured at all times.[30] The Medical Board defines "area that is secure" to mean a locked storage area within a physician's office. • Keys to locked storage area are available only to staff authorized by the physician to have access.[31] • The Medical Board of California interprets "all drugs" to also include both sample and over-the-counter drugs.[32] **IV.A.2) Drugs, drug samples, and over-the-counter drugs, hypodermic needles/syringes, all medical sharp instruments, hazardous substances and prescription pads are securely stored in a lockable space (cabinet or room) within the office/clinic.** • All drugs (including sample and over the counter), medication supplies, hazardous substances and prescription pads are securely stored in a lockable space (room, closet, cabinet, drawer) within the office/clinic.[33] (CA B&P Code, 4051.3) • A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. (42 CFR 482.13-CMS Manual System; 42 CFR Part 482.25) • Keys to the locked storage area are available only to staff authorized by the physician to have access.[34] (16 CCR, Chapter 2, Division 3, Section 1356.32) • During business hours, the lockable space may remain unlocked ONLY if there is no access to

[30] BPC 4172
[31] 16 CCR 1356.3
[32] 22 CCR 75032 and 75033
[33] BPC 4051.3
[34] 16 CCR 1356.32

Criteria	IV. Clinical Services - Pharmaceutical Standards
	this area by unauthorized persons and authorized clinic personnel remain in the immediate area at all times. At all other times, all drugs (including sample and over the counter), medication supplies, prescription pads and hazardous substances must be securely locked. **IV.A.3) Controlled drugs are stored in a locked space accessible only to authorized personnel.** **<u>Controlled substances</u>**: • Controlled substances are stored separately from other drugs in a securely locked, substantially constructed cabinet accessible only to authorized personnel.[35] **IV.A.4) A dose-by-dose controlled substance distribution log is maintained.** • Written records are maintained of controlled substances inventory list(s) that includes: 1) Provider's DEA number 2) Name of medication 3) Original quantity of drug 4) Dose 5) Date 6) Name of patient receiving drug 7) Name of authorized person dispensing drug and 8) Number of remaining doses • Control substances include all Schedule I, II, III, IV, and V substances listed in the CA Health and Safety Code, Sections 11053-11058, and do not need to be double locked. • Personnel with authorized access to controlled substances include physicians, dentists, podiatrists, PAs, licensed nurses, and pharmacists and specifically authorized employees.[36] **IV.A.5) Written site-specific policy/procedure for dispensing of sample drugs are available on site.** • A list of drugs available for use in the clinic shall be maintained. Site should have written site-specific policies and procedures (P&Ps) for use of sample medications including governing activities of pharmaceutical manufacturers' representatives American Society of hospital

[35] 21 CFR 1301.75
[36] 21 CFR 1301.72

Criteria	IV. Clinical Services - Pharmaceutical Standards
	pharmacist (ASHP) Guidelines: Minimum Standard for pharmaceutical services in ambulatory care).[37] • Each clinic, which provides drug distribution services, shall have written policy and procedures for the safe and effective distribution, control, storage, use and disposition of drugs. **Note:** During business hours, the drawer, cabinet or room containing drugs, medication supplies or hazardous substances may remain unlocked ***only*** if there is no access to area by unauthorized persons. Whenever drugs, medication supplies or hazardous substances are unlocked, authorized clinic personnel must ***always remain*** in the immediate area. At all other times, drugs, medication supplies, and hazardous substances must be securely locked. Controlled substances are ***always locked***.
B. Drugs are handled safely and stored appropriately. **RN/NP/CNM/LM/MD/PA**	**Deficiencies:** All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, etc.) must be addressed in a corrective action plan (CAP). **IV.B.1) Drugs are prepared in a clean area or "designated clean" area if prepared in a multi-purpose room.** **Drug Preparation:** Drugs shall be drawn up in a designated clean medication preparation area that is not adjacent to potential sources of contamination, including sinks or other water sources. The drug preparation area should be cleaned and disinfected on a regular basis. CDC guidelines for drug preparation and safety: https://www.cdc.gov/injectionsafety/providers/provider_faqs_med-prep.html **IV.B.2) Drugs for external use are stored separately from drugs for internal use.** **Storage:** • Drugs shall be separated by route of administration, especially ophthalmic and otic preparations. • Vaccines and other drugs should be stored separately from food, lab specimens, human specimens, cleaning supplies, and other items that may potentially cause contamination.

[37] The ASHP Guidelines for Minimum Standard for Ambulatory Care Pharmacy Practice is available at: https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/anticoagulation/guidelines-minimum-standard-ambulatory-care-pharmacy.ashx?la=en&hash=ABF816352CAF1AB846B7C339A45AA74D80F820A6.

Criteria	IV. Clinical Services - Pharmaceutical Standards

	• The Center for Disease Control (CDC) recommends avoiding storing other medications and biological products such as lab specimens/human specimens in a vaccine storage unit.
	
	IV.B.3) Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.
	• Storing food, other medications, and biological products with vaccines put vaccines at risk for temperature fluctuation, excessive light exposure, administration errors, and contamination.
	  ○ If food, other medications and biological products must be stored in the same refrigerator with vaccines, they must be in the sealed containers and stored below vaccines on the different shelves.
	• Drugs are stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug product are not affected.[38]
	• Room temperature where drugs are stored does not exceed 30ºC (86ºF).[39]
	• A drug or device is considered "adulterated" if it contains any filthy, putrid, or decomposed substance, or if it has been prepared, packed or held under unsanitary conditions.[40]
	• A drug is considered contaminated if it has been held under unsanitary conditions that may have been contaminated with filth or rendered injurious to health.
	• Drugs that are unused are considered by the Environmental Protection Agency (EPA) to be toxic wastes and must be disposed in accordance with 40 CFR, part 261.
	
	American College of Physician guidelines state sound management procedures include:
	  ○ Routinely checking for expiration dates.
	  ○ Keeping medicines off the floor.
	  ○ Labeling the sample medicines or writing prescribing information directly on the sample package.
	  ○ Keeping a log of sample medicines given. In case of a recall, keeping a log allows to track down a patient to whom the recalled drug had been prescribed.
	  ○ When a medication sample is given to a patient, the name and strength of the medication, instructions for use and the quantity or duration of therapy is always documented in the patient's chart.

[38] 21 CFR 211.142
[39] 22 CCR 75037(d)
[40] Title 21, United States Code (USC), section 351. USC is searchable at: https://uscode.house.gov/search/criteria.shtml.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	ASHP guidelines for minimum standard for pharmaceutical services in ambulatory care: ○ Site should have written site-specific policies and procedures (P&Ps) for use of sample medications including governing activities of pharmaceutical manufacturers' representatives. ○ Each clinic, which provides drug distribution services, shall have written policy and procedures for the safe and effective distribution, control, storage, use and disposition of drugs.[41] **Immunobiologics:**[42] • Sites should have a written Vaccine Management Plan for routine and emergency vaccine management (required for Vaccines for Children (VFC) providers). • Vaccines are refrigerated immediately upon receipt on site and stored according to specific instructions on the package insert for each vaccine. • Diluent does not need refrigeration if vaccine is administered right after diluent is added. • Vaccines are not stored in the doors, floors, vegetable bins, or under or near cooling vents of a refrigerator or freezer. **IV.B.4) Refrigerator thermometer temperature is 36º-46º Fahrenheit or 2º-8º Centigrade (at time of site visit).** **Refrigerator:** Vaccines are kept in a refrigerator **maintained at 2-8ºC or 36-46ºF,** and include, but are not limited to, DTaP, Td, Tdap, Hepatitis A, Hepatitis B, IPV, Pneumococcal, Rotavirus, Hib, Influenza (inactivated and FluMist), MCV, HPV, recombinant Zoster, or any combinations of these listed vaccines.[43] **IV.B. 5) Freezer thermometer temperature is 5º Fahrenheit or –15º Centigrade, or lower (at time of site visit).**

[41] The ASHP Guidelines for Minimum Standard for Ambulatory Care Pharmacy Practice is available at: https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/anticoagulation/guidelines-minimum-standard-ambulatory-care-pharmacy.ashx?la=en&hash=ABF816352CAF1AB846B7C339A45AA74D80F820A6.
[42] See the FDA's webpage on Vaccines, available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/questions-about-vaccines.
[43] See the CDC Vaccine Recommendation and Guidelines of the Advisory Committee on Immunization Practices, available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html, and the CDC Vaccine Storage and Handling Toolkit, available at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<u>Freezer:</u> Varicella and MMRV vaccines are stored in the **freezer at -15ºC or 5ºF, or lower,** and are always protected from light. ○ MMR may be stored in a refrigerator or freezer; VFC recommends MMR be stored in the freezer with MMRV. ○ Never freeze vaccine diluents. **IV.B. 6) Site utilizes drugs/vaccine storage units that are able to maintain required temperature.** CDC recommends for both temporary and long-term storage refrigerators and freezers using: ○ Purpose-built units designed to either refrigerate or freeze (can be compact, under-the counter style or large units). ○ Stand-alone household units. ○ Units dedicated to storage of biologics. Measures should be in place to ensure that vaccine storage units are not accidentally physically disconnected from the power supply, such as “Do Not Disconnect” labels and not plugging units into surge protectors with an on/off switch. **Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.[44]** **IV.B. 7) Daily temperature readings of drugs/vaccines refrigerator and freezer are documented.** Refrigerator and freezer temperatures are documented at least once a day (required twice daily for VFC providers). CDC recommends use of a continuous temperature monitoring device (digital data loggers). ○ Digital data loggers (DDL) should have a minimum accuracy of +/- 1°F (0.5°C) ○ Equipped with buffered probe ○ Active temperature display outside of the unit ○ Capacity for continuous monitoring and recording where the data can be routinely downloaded ○ Calibrated at least every 2 years, to monitor vaccine storage unit temperatures

[44] See the CDC Vaccine & Immunization webpage, available at: https://www.cdc.gov/vaccines/.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	At least one back-up device should be readily available for emergency vaccine transport or when primary DDL is sent in for calibration. **IV.B. 8) Has a written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer.** • A written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer is required. www.cdc.gov https://www.cdc.gov/disasters/poweroutage/vaccinestorage.html • Site personnel must be able to verbalize the procedures in the plan used to promptly respond to OUT OF RANGE TEMPERATURES. • Quarantine vaccines until guidance is obtained. • Action is taken when temperatures are identified to be outside of the recommended range. • Contacting VFC (http://eziz.org/vfc/overview/) or manufacturer are acceptable procedures. • For VFC providers, follow program requirements for documentation and reporting. Consultation with CDC is available when necessary.[45] www.cdc.gov **IV.B. 9) Drugs and vaccines are stored separately from test reagents, germicides, disinfectants, and other household substances.** • As these items may potentially cause contamination to verify that drugs are stored separately from test reagents, germicides, disinfectants, and other household substances. **IV.B.10) Hazardous substances are appropriately labeled.** **IV.B.11) Site has method(s) in place for drug and hazardous substance disposal.** **Hazardous Substances Labeling and Disposal**: • Safety practices are followed in accordance with current/updated CAL-OSHA standards and 29 CFR 1910.1030.

[45] See the CDC General Best Practice Guidelines for Immunization: Best Practices Guidance of the ACIP, available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html, the CDC Vaccine Storage and Handling Toolkit, available at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf, the FDA Questions about Vaccines, available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/questions-about-vaccines, and the CDC webpage on Vaccines and Immunizations, available at: https://www.cdc.gov/vaccines/.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	• The manufacturer's label is not removed from a container (bag, bottle, box, can, cylinder, etc.) only if the hazardous material or residues of the material remain in the container. • Containers for biohazard waste shall comply with United States Department of Transportation requirements when prepared for transport offsite from the facility. • A hazardous waste transporter transporting medical waste shall maintain a completed tracking document and provide a copy of that document to the medical waste generator (clinic, etc.). All portable containers of hazardous chemicals and secondary containers into which hazardous substances are transferred or prepared require labeling. Labels must provide the following information: 1) Identity of hazardous substance 2) Description of hazard warning: can be words, pictures, symbols 3) Date of preparation or transfer **Exception**: Labeling is not required for portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the individual who performs the transfer. **Note:** The purpose of hazard communication is to convey information about hazardous substances used in the workplace. A hazardous substance is any substance that is a physical or health hazard.
C. Drugs are dispensed according to State and federal drug distribution laws and regulations. **RN/NP/CNM/LM/MD/PA**	**Deficiencies:** All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, etc.) must be addressed in a corrective action plan. **IV.C.1) There are no expired drugs on site.** **Expiration Date:** • The manufacturer's expiration date must appear on the labeling of all drugs and formulas. • All prescription drugs not bearing the expiration date are deemed to have expired. • If a drug is to be reconstituted at the time of dispensing, its labeling must contain expiration information for both the reconstituted and unreconstituted drug. • Expired drugs may not be distributed or dispensed. • Per CDC – Medication Vials should be discarded whenever sterility is compromised or questionable.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	• Per CDC "If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial". • Per VFC "For multi-dose vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial unless otherwise specified by the manufacturer (Polio, meningococcal polysaccharide vaccine (MPSV4), PPSV, TIV, IPV, and yellow fever that are available in multi-dose vials)".[46] Both CDC and VFC recommend to follow the manufacturer's product information. **IV.C.2) Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas.** • Site has a procedure to check expiration date of all drugs (including vaccines and samples) and infant and therapeutic formula AT LEAST monthly. **IV.C.3) All stored and dispensed prescription drugs are appropriately labeled.** **Prescription Labeling**: • Labels shall be carefully preserved, and all medications shall be stored in their original containers. • Each prescription medication dispensed is in a container that is not cracked, soiled, or without secure closures.[47] • Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. • Drug container is labeled with the provider's name, patient's name, drug name, dose, frequency, route, quantity dispensed, and manufacturer's name and lot number. • California Pharmacy Law *does not* prohibit furnishing a limited quantity of sample drugs if dispensed to the patient in the package provided by the manufacturer, no charge is made to the patient, and appropriate documentation is made in the patient's medical record.[48]

[46] See the CDC Frequently Asked Questions regarding Multi-dose vials, available at: https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html, and the CDC Vaccine Storage and Handling Toolkit, available at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
[47] 22 CCR 75037(A)
[48] BPC 4170 and 4171

Criteria	IV. Clinical Services - Pharmaceutical Standards
	Drug Distribution: • Each clinic that provides drug distribution services has written policies and procedures for the safe and effective distribution control, storage, use and disposition of drugs. • In order to prevent inadvertent exposure to out-of-range temperatures, vaccines should never be re-distributed beyond the manufacturer/distributer-to-clinic distribution chain unless during an emergency. • In the event of necessary vaccine transport (emergency/power outage), vaccines must be packaged following CDC recommendations and include temperature monitoring devices during transport (approval is required for VFC providers prior to any vaccine transfer). **IV.C.4) (CE) Only lawfully authorized persons dispense drugs to patients.** **Drug Dispensing:** • Drug dispensing complies with all applicable State and federal laws and regulations. • Drugs are dispensed only by a physician, pharmacist, or other persons (e.g., NP, CNM, RN, PA) lawfully authorized to dispense medications upon the order of a licensed physician or surgeon. • Personnel such as MAs, office managers, and receptionists do not dispense drugs. • Drugs are not offered for sale, charged or billed to Medi-Cal members.[49] • A record of all drugs and formulas dispensed shall be entered in the patient's medical record. **Drug Administration:** • Basic safe practices for medication/vaccine administration, assess and document: 1) Patient's identity 2) Correct medication 3) Correct dose 4) Correct route 5) Appropriate time CMS Manual System;[50] • Proper preparation is critical for maintaining the integrity of the vaccine during transfer from the vial to the syringe.

[49] BPC 4193
[50] 42 CFR 482.23(c)

Criteria	IV. Clinical Services - Pharmaceutical Standards
	• Personnel can demonstrate or verbally explain procedure(s) used on site to confirm correct patient, medication/vaccine, dosage and route and vaccine are prepared and drawn only prior to administration. • Proper vaccine administration is critical to ensure that vaccination is safe and effective. • CDC recommends that all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration policies and procedures before administering vaccines. • Comprehensive, skills-based training should be integrated into existing staff education programs such as new staff orientation and annual education requirements. **IV.C.5) (CE) Drugs and Vaccines are prepared and drawn only prior to administration.** ACIP discourages the routine practice of providers' prefilling syringes. • Vaccines have a similar appearance after being drawn into a syringe, prefilling may result in administration errors. • Unused, provider prefilled syringes must be discarded if not used within the same day that they are filled. • Unused syringes that are prefilled by the manufacturer and activated (i.e., syringe cap removed, or needle attached) should be discarded at the end of the clinic day. In certain circumstances in which a single vaccine type is being used (e.g., in preparation for a community influenza vaccination campaign), filling a small number (10 or fewer) of syringes may be considered (*5*). The doses should be administered as soon as possible after filling, by the same person who filled the syringes. The Center for Biologics Evaluation and Research (CBER) at the FDA offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions.[51] **IV.C.6) Current Vaccine Information Sheets (VIS) for distribution to patients are present on site.** **Vaccine Immunization Statements**:

[51] See the CDC's Vaccine Recommendations and Guidelines of the ACIP, available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	• Since 1994, the National Childhood Vaccine Injury Act, Section 2126 of the Public Health Service Act, mandates that parents/guardians or adult patients be informed before vaccinations are administered. • Health care providers must present and offer a VIS to patients prior to any vaccine.[52] As of 2009, CDC allows providers to present a current VIS (such as a laminated copy in a binder, etc.) to the patient/parent/guardian and allow time for the patient to read and ask questions. Staff should also offer a copy each time.[53] • The date the VIS was given (or presented and offered) *and* the publication date of the VIS must be documented in the patient's medical record. • Federal law allows up to 6 months for a new VIS to be used. The most current VIS are available from state and local health departments or can be downloaded from the CDC web site at: http://www.cdc.gov/vaccines/pubs/vis/default.htm or by calling the CDC Immunization Hotline at (800) 232-2522. VFC contains current VIS and provider notifications at: http://www.eziz.org/ **IV.C.7) If there is a pharmacy on site, it is licensed by the CA State Board of Pharmacy.** **Pharmacy:** • If a pharmacy is located on site and owned by the clinic, the license issued by the CA State Board of Pharmacy must be present on site. • Every pharmacy that dispenses a controlled substance must be registered with the DEA and be licensed by the CA State Board of Pharmacy. • A licensed pharmacist monitors drug distribution and policies and procedures for medication dispensing and storage. **Note:** "Dispensing" of drugs means the furnishing of drugs or devices directly to a patient or upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or upon an order to furnish drugs or transmit a prescription from a certified nurse midwife, nurse practitioner, physician assistant or pharmacist acting within the scope of his or her practice. **IV.C.8) Site utilizes California Immunization Registry (CAIR) or the most current version.**

[52] 42 USC 300aa-26(D)(2)
[53] See the CDC's Facts about VIS, which is available at: https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<u>Immunization Registry Utilization</u>: Scoring must be No or Yes. • DHCS requires documentation of immunizations in the California CAIR or the local registry. • If the clinic does not offer vaccines administration, the site staff shall be able to utilize the registry to access the member's immunization record. Contractor shall ensure that member-specific immunization information is periodically reported to an immunization registry (is) established in the Contractor's Service Area(s) as part of the Statewide Immunization Information System. Reports shall be made following the Member's initial health assessment and all other health care visits which result in an immunization being provided. Reporting shall be in accordance with all applicable State and Federal laws. DHCS Contract; CDC Recommendations at: www.cdc.gov/vaccines.

Criteria	IV. Clinical Services – Laboratory Review
D. Site is compliant with Clinical Laboratory Improvement Amendment (CLIA) regulations.	**IV.D.1) Laboratory test procedures are performed according to current site-specific CLIA certificate.** **<u>CLIA Certificates</u>**: • All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease has a current, unrevoked, unsuspended site-specific Clinical Laboratory Improvement Amendment (CLIA) certificate, or evidence of renewal. • Acceptable documentation such as the original certificate, copy of the original certificate, renewal receipt or other evidence of renewal submission is present on site or readily available upon request. The CLIA certificate or evidence of renewal should include the current site/clinic address. **<u>Note</u>:** Per 42 CFR, 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3), laboratories must file a separate application for each laboratory location, with the following *<u>exceptions</u>*: 1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address. 2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application, or 3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for laboratory sites within same physical location or street address. 4) A multi-site CLIA waiver can be used at all affiliated locations. A copy of the CLIA waiver must be at each individual location with the address of the main location on the waiver. A copy of the CLIA application must be reviewed by the CSR to verify the locations included for old and new locations. The CLIA Certificate on site includes one of the following: ○ Certificate of Waiver: Site can perform only exempt waived tests ○ Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists, or NPMPs can perform PPM procedures and waived tests

Criteria	IV. Clinical Services – Laboratory Review
	○ Certificate of Registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations are determined by survey ○ Certificate of Compliance: Lab has been surveyed and found in compliance with all applicable CLIA requirements ○ Certificate of Accreditation: Lab is accredited by an accreditation organization approved by CMS **Waived Tests**: • If only waived tests are performed, site has a current CLIA Certificate of Waiver. • There are no specific CLIA regulations regarding the performance of waived tests. • Site personnel are expected to follow the test manufacturer's instructions. • Laboratories with certificates of waiver may not be routinely inspected by DHCS Laboratory Field Services Division but may be inspected as part of complaint investigations and on a random basis to determine whether only waived tests are being performed. **Moderate and High Complexity Tests:** Tests not listed as waived are divided into one of two categories, moderate complexity or high complexity, based on the complexity of the testing procedure. CLIA regulations for these categories list specific requirements for laboratory proficiency testing, patient test management, quality control, quality assurance, personnel, and inspections. **IV.D.2) Testing personnel performing clinical lab procedures have been trained.** **Personnel Training:** • Prior to testing biological specimens, personnel have been appropriately trained for the type and complexity of the laboratory services performed. • Personnel have demonstrated the ability to perform all testing operations reliably and to report results accurately. • Site personnel that perform CLIA waived tests have access to and can follow test manufacturer's instructions. • When requested, site personnel can provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.

Criteria	IV. Clinical Services – Laboratory Review
	• The required training and certification are established by legislation for personnel performing moderate and high complexity tests.[54] Reviewers are not expected to complete an in-depth evaluation of personnel performing moderate and high complexity tests. **IV.D.3) Lab supplies (e.g. vacutainers, vacutainer tubes, culture swabs, test solutions) are inaccessible to unauthorized persons.** **IV.D.4) Lab test supplies are not expired.** Lab supplies are disposed of by manufacturer's expiration date. **IV.D.5) Site has a procedure to check expiration date and a method to dispose of expired lab test supplies.** **Note:** Any site that performs tests or examinations on human biological specimens derived from the human body is, by definition, "laboratories" under State and federal law, and includes locations such as nurses' stations within hospitals, clinics, surgical centers, physician offices, and health fairs. The current listing of waived tests may be obtained at www.cms.gov or www.fda.gov includes an evaluation every two years (or sooner of complaint driven) by CDPH of personnel licenses/training, laboratory site inspection and demonstration of testing proficiency for moderate and high-complexity test sites. **Contact CDPH Laboratory Field Services (510) 620-3800 or LFSrecep@cdph.ca.gov for CLIA certification, laboratory license, or personnel questions.**

[54] BPC 1200-1213

Criteria	IV. Clinical Services – Radiology Review
E. Site meets CDPH Radiological inspection and safety regulations	**IV.E.1) Site has current CA Radiologic Health Branch Inspection Report and Proof of Registration if there is radiological equipment on site.** **<u>CDPH Radiologic Health Branch (RHB) Inspection Report</u>**: If site has ***current*** documentation of one of the following, give the full 9 points and survey items 2-9 will not need to be surveyed. Acceptable documentation is: ○ Inspection Report and Proof of Registration, ***or*** ○ Inspection Report and Proof of Registration *and* Short Form Sign-off sheet, ***or*** ○ Inspection Report and Proof of Registration *and* Notice of Violation form *and* approval letter for corrective action plan from the CA RHB The Radiologic Inspection Report and Proof of Registration (receipt of payment or cancelled check), issued by the RHB, must be present if there is radiology equipment on site. If any violations are found, one of two documents are issued to the site: ○ "Short Form Sign-off sheet" is issued for minimal problems that are easily corrected. ○ "Notice of Violation" form, requiring a site corrective action plan, is issued if there are more violations that are serious. All "Notice of Violation" corrective action plans must be accompanied by an approval letter from the CA RHB. **If documents are not available on site, or if reviewer is uncertain about the "status of documents on site, proceed to score all items 1-9.** **The following documents are posted on site:** **IV.E.2) Current copy of Title 17 with a posted notice about availability of Title 17 and its location.** **IV.E.3) "Radiation Safety Operating Procedures" posted in highly visible location.** **IV.E.4) "Notice to Employees Poster" posted in highly visible location.** **IV.E.5) "Caution, X-ray" sign posted on or next to door of each room that has X-ray equipment.** **IV.E.6) Physician Supervisor/Operator certificate posted and within current expiration date.**

Criteria	IV. Clinical Services – Radiology Review
	IV.E.7) Technologist certificate posted and within current expiration date. **The following radiological protective equipment is present on site:** **IV.E.8) Operator protection devices: radiological equipment operator must use lead apron or lead shield.** **IV.E.9) Gonadal shield (0.5 mm or greater lead equivalent): for patient procedures in which gonads are in direct beam.** **Radiological Equipment:** Equipment inspection, based on a "priority" rating system, is established by legislation. https://blink.ucsd.edu/_files/safety-tab/rad/Title-17-CCR.pdf • Mammography equipment is inspected annually, and must have federal FDA Certification on site ***and*** CA Mammography X-ray Equipment and Facility Accreditation Certification posted on the machine.[55] • High Priority equipment (e.g. fluoroscopy, portable X-ray) is inspected every three years. • Medium Priority equipment is inspected every 4-5 years depending on the volume of patients, frequency of x-ray equipment uses, and likelihood of radiation exposure. If reviewer is uncertain about the "status of equipment inspection, call the RHB. **Radiology Personnel:** • All certificates/licenses are posted and show expiration dates. • If there are many technicians, a list of names, license numbers, and expiration dates may be substituted. • The Certified Radiological Technologist (CRT) certificate permits the technologist to perform all radiology films except mammography and fluoroscopy, which require separate certificates. • The "Limited Permit" restricts the technician to one of the ten-(10) x-ray categories specified on the limited certificate: Chest, Dental laboratory, Dermatology, Extremities, Gastrointestinal, Genitourinary, Leg-podiatric, Skull, Torso-skeletal, and X-ray bone densitometry.

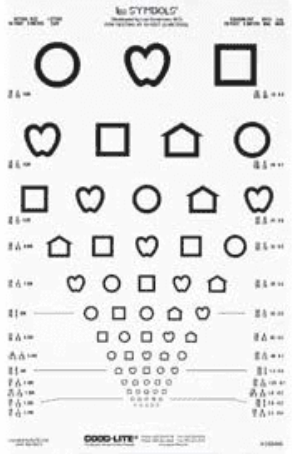
[55] 21 CFR 900

Criteria	IV. Clinical Services – Radiology Review
	Note: • Per RHB, dexascanners do not require lead aprons or gonadal shields, however, criteria 1-7 are still required. • RHB uses the ALARA (As Low As Reasonably Achievable) principle, which is the foundation of all radiation safety programs. The ALARA principle means to minimize exposure to radiation doses by employing all *reasonable* methods. • Dexascanners manufacturer guidelines do not require gonadal shielding or lead aprons due to very low radiation output, and potential for the shield to obscure the area being scanned, possibly rendering the scan non-diagnostic. With the focused beam, operators do not need aprons, the amount of exposure of "scattered" beams to an operator seated near the scanner is about the same level as that found in the natural environment. A traditional x-ray machine used for bone density testing, is not a dexascanner, and *may* require shielding/apron. **Note:** The RHB of the Food, Drug, and Radiation Safety Division of CDPH enforces the Radiation Control Laws and Regulations designed to protect both the public and employees against radiation hazards. Enforcement is carried out through licensing, registration and periodic inspection of sources of radiation, such as radiation machines. For questions regarding radiologic safety (e.g. expired or no inspection letters on site), call CDPH RHB at (916) 327-5106. For Radiation Emergency Assistance, call 1-800-*852*-7550. Ref: CCR, Title 17, Chapter 5, Subchapter 4 regulations at https://www.cdph.ca.gov/rhb

Criteria	V. Preventive Services Standards
A. Preventive health care services and health appraisal examinations are provided on a periodic basis for the detection of asymptomatic diseases.	**Examination equipment, appropriate for primary care services, is available on site:** **V.A.1) Exam tables and lights are in good repair.** **<u>Examination Table and Lights</u>:** • Lights and exam tables shall be in good repair. "Good repair" means clean and well maintained in proper working order. • Examination tables must have a protective barrier such as paper which is changed between patients, to cover the exam surface. **V.A.2) Stethoscope and sphygmomanometer with various size cuffs (e.g. child, adult, obese, thigh).** **V.A.3) Thermometer with a numeric reading.** **V.A.4) Basic exam equipment: in addition to items mentioned above, offices should have the following:** o Percussion hammer o Tongue blades o Patient gowns **V.A.5) Scales: Standing balance beam and infant scales.** **<u>Scales:</u>** • Infant scales are marked and accurate to increments of one (1) ounce or less and have a capacity of at least 35 pounds. • Standing floor scales are marked and accurate to increments of one-fourth (1/4) pound or less and have a capacity of at least 300 pounds. • Balance beam scales have an adjustment mechanism and zeroing weight to enable routine balancing at zero. • Electronic or digital scales have automatic zeroing and lock-in weight features. • Spring balance scales (e.g. bathroom scales) are unsatisfactory for clinical use as, over time, the spring counterbalance mechanism loses its accuracy.

Criteria	V. Preventive Services Standards
	V.A.6) Measuring devices for stature (height/length) measurement and head circumference measurement. **Measuring Devices:** Equipment on site for measuring stature (length/height) and head circumference includes: ○ Rigid 90º right angle headboard block that is perpendicular to the recumbent measurement surface. ○ Vertical to the wall-mounted standing measurement surface. ○ Flat, paper or plastic non-stretchable tape or yardstick, marked to one-eighth (1/8 in. or 1 mm) or less, attached to a firm, flat surface. The "0" of the tape is exactly at the base of the headboard for recumbent measurement, or exactly at foot level for standing measurement. ○ Moveable, non-flexible footboard at 90º right angle perpendicular to the recumbent measurement surface, or a flat floor surface for standing. ○ A non-stretchable tape measuring device marked to one-eighth (1/8 in. or 1 mm) or less for measuring head circumference (re-usable measuring device must be appropriately cleaned in between use). **V.A.7) Eye charts (literate and illiterate) and occluder for vision testing.** **Vision Testing:**[56] • Site has both literate (e.g., Snellen) and illiterate eye charts • The current preferred optotypes (figures or letters of different sizes) for patients who cannot distinguish letters are the LEA or HOTV symbols (see figures below)

[56] See the Procedures for the Evaluation of the Visual System by Pediatricians, available at: https://pediatrics.aappublications.org/content/137/1/e20153597. Also see the American Association for Pediatric Ophthalmology and Strabismus Vision Screening Committee's Pediatric Screening Guidance during the COVID-19 Pandemic, available at: https://aapos.org/education/allied-health/covid.

Criteria	V. Preventive Services Standards
	  • Wall mounted eye charts should be height adjustable and positioned at the eye-level of the patient • Examiners shall stand their patients with their heels to the line unless the eye chart that is being used to screen specifically instructs the patient to be positioned elsewhere. “Heel” lines are aligned with center of eye chart at 10 or 20-feet depending on whether the chart is for the 10-foot or 20-foot distance. • Eye charts are in an area with adequate lighting and at height(s) appropriate to use • Effective occlusion, such as with tape or an occlusive patch of the eye not being tested, is important to eliminate the possibility of peeking. **V.A.8) Ophthalmoscope.** Ophthalmoscope is in good working condition. **V.A.9) Otoscope with adult and pediatric ear speculums.** Otoscope with multi-size ear speculums appropriate to the population served. **V.A.10) A pure tone, air conduction audiometer is located in a quiet location for testing.**

Criteria	V. Preventive Services Standards

	Hearing Testing:[57]
	• The pure tone audiometer must have the minimum ability to:
	  ○ Produce intensities between 0 to 80 dB
	  ○ Have a headset with right and left earphones
	  ○ Be operated manually
	  ○ Produce frequencies at 1000, 2000, 3000, 4000, 6000, and 8000 Hz
	• Offices that provide pediatric preventive services should have a pure tone; air conduction audiometer available, audiometric testing is required at preventive health visits starting at 4 years of age.
	• PCP offices (such as Family Practitioners or General Practitioners) that refer all members to another provider for audiometric testing, must have a system in place that clearly demonstrates that the PCP office verifies that audiometric testing has been completed and that those results are returned to the PCP for review.

B. Health education services are available to Plan members.	**Health Education Services:** Services may include individual instruction, group classes, family counseling and/or other health educational programs and materials provided to members by the provider, health plan, or community sponsored programs. **Health education materials and Plan-specific resource information are:** **V.B.1) Readily accessible on site or are made available upon request.** **V.B.2) Applicable to the practice and population served on site.** **V.B.3) Available in threshold languages identified for county and/or area of site location.** **Health Education Materials:**

[57] See the American Speech-Language-Hearing Association's guidance on Audiograms, available at: https://www.asha.org/public/hearing/audiogram/.

Criteria	V. Preventive Services Standards
	• Must be available in the appropriate threshold languages and may be located in an accessible area on site (e.g., exam room, waiting room, health education room or area), or provided to members by clinic staff and/or by Plan upon request. • Must be available in accessible format which may include written information, audio and/or videotapes, computerized programs, and visual presentation aids for people with disabilities. • Should include general topics for health educational material such as: Immunizations, Pregnancy, Injury Prevention, Smoking Cessation, Dental Health, Nutrition, Physical Activity, STD/HIV Prevention, Family Planning, Asthma, Hypertension, and Diabetes. • Must meet the Medi-Cal Managed Care readability and suitability requirements for educational material distributed to Medi-Cal members.[58] **Plan-Specific Referral Information:** Plan-specific informing materials and/or resources are available on site in languages that are applicable to member population(s) primarily seen on site. ○ For example, if primarily English and Spanish-speaking members are seen on site, then Plan-specific informing materials are available on site in those languages. ○ Although a site may not stock informing materials in each threshold language identified for the county, site personnel has access to contact resource information for locating Plan-specific informing materials in threshold languages not typically seen on site. ○ Interpreter services are provided in all identified threshold and concentration standard languages. **Note:** Threshold languages are the primary languages spoken by Limited English Proficient (LEP) population groups residing in a county. A numeric threshold of 3,000 eligible LEP Medi-Cal beneficiaries or a concentration standard of 1,000 residing in a single ZIP code or 1,500 in two contiguous ZIP codes establishes the threshold languages identified by DHCS for each county.

[58] See All Plan Letter (APL) 18-016, "Readability and Suitability of Written Health Education Materials". APLs are searchable at: https://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx.

Criteria	VI. Infection Control Standards
A. Infection control procedures for Standard/Universal precautions are followed. 🔍 🗁 **RN/NP/CNM/LM/MD/PA**	**Deficiencies:** All deficiencies related to Infection Control must be addressed in a corrective action plan (CAP). **Hand Washing Facilities:**[59] • Hand washing facilities are available in the exam room and/or utility room, and include an adequate supply of running potable water, soap and single use towels or hot air-drying machines. • Sinks with a standard faucet, foot-operated pedals, 4-6-inch wing-type handle, automatic shut-off systems or other types of water flow control mechanism are acceptable. • Staff can demonstrate infection control "barrier" methods used on site to prevent contamination of faucet handle, door handles and other surfaces until hand washing can be performed. • On occasions when running water is not readily available, an antiseptic hand cleanser, alcohol-based hand rub, or antiseptic towelettes is acceptable until running water is available.[60] **VI.A.1) Soap or antiseptic hand cleaner and running water are available in exam and/or treatment areas for hand washing.** **Soap or Antiseptic Hand Cleaner:** Hand washing prevents infection transmission by removing dirt, organic material and transient microorganisms from hands. ○ Hand washing with plain (non-antimicrobial) soap in any form (e.g., bar, leaflet, liquid, powder, granular) is acceptable for general patient care (Association for Professionals in Infection Control and Epidemiology, Inc., 1995). ○ Antimicrobial agents or alcohol-based antiseptic hand rubs are used for hand washing when indicated to remove debris and destroy transient microorganisms (e.g., before performing invasive procedures, after contact with potentially infectious materials). ○ Plain and antiseptic hand wash products are properly maintained and/or dispensed to prevent contamination.

[59] See the World Health Organization's Hand Hygiene guidelines, available at: https://www.who.int/gpsc/5may/Hand_Hygiene_Why_How_and_When_Brochure.pdf.
[60] 29 CFR 1919.1030

Criteria	VI. Infection Control Standards
	VI.A.2) A waste disposal container is available in exam rooms, procedure/treatment rooms, and restrooms. **Waste Disposal Container:**[61] • Contaminated wastes (e.g. dental drapes, band-aids, sanitary napkins, soiled disposable diapers) are disposed of in regular solid waste (trash) containers, and are maintained to prevent potential contamination of patient/staff areas and/or unsafe access by infants/children. • Closed containers are not required for regular, solid waste trash containers. **VI.A.3) Site has procedure for effectively isolating infectious patients with potential communicable conditions.** **Isolation Procedures**:[62] • Personnel can demonstrate or verbally explain procedure(s) used on site to isolate patients with potentially contagious conditions from other patients. • If personnel are unable to demonstrate or explain site-specific isolation procedures *and* cannot locate written isolation procedure instructions, site is considered deficient. • Isolation procedures may vary from site to site. **Note:** • Infection Control standards are practiced on site to minimize risk of disease transmission. • Site personnel are expected to apply the principles of "Standard Precautions" (CDC, 1996), used for all patients regardless of infection status. • Standard precautions apply to blood, all body fluids, non-intact skin, and mucous membranes, which are treated as potentially infectious for HIV, HBV or HCV, and other bloodborne pathogens. • "Universal precautions" refer to the OSHA mandated program that requires implementation of work practice controls, engineering controls, bloodborne pathogen orientation/education, and record keeping in healthcare facilities.

[61] HSC 118275-118320. Also see the OSHA Standards for Bloodborne Pathogens, available at: https://www.hercenter.org/rmw/osha-bps.php.

[62] See the CDC's Guidelines for Isolation Precautions, available at: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html.

Criteria	VI. Infection Control Standards
B. Site is compliant with OSHA Bloodborne Pathogens Standard and Waste Management Act. 🗁 **RN/NP/CNM/LM/MD/PA**	**Deficiencies:** All deficiencies related to Infection Control must be addressed in a corrective action plan. **VI.B.1) (CE) Personal Protective Equipment for Standard Precautions is readily available for staff use.** **Personal Protective Equipment (PPE):** PPE must be readily available.[63] PPE for protection against bloodborne pathogen hazards is available on site and must include: 1) Gloves 2) Water repellent clothing barrier/gown 3) Face/eye protection (e.g., goggles/face shield) 4) Respiratory infection protection (e.g., mask) PPE does not include general work clothes (e.g., uniforms, cloth lab coats) that will permit liquid to soak through. • The storage of PPE should be adequate to protect the PPE from contamination, loss, damage, water or sunlight. • Proper storage often requires a dry and clean place that is not subject to temperature extremes. **VI.B.2) (CE) Blood, other potentially infectious materials, and Regulated Wastes are placed in appropriate leak proof, labeled containers for collection, handling, processing, storage, transport or shipping.** **Blood and Other Potentially Infectious Materials (OPIM):** • OPIM are all human body fluids, any unfixed tissue or organ (other than intact skin) from a human (living or dead), and HIV or HBV-containing blood, cells, tissue, organs, cultures, medium or solutions. • Containers for blood and OPIM are closable, leak proof, and labeled and/or color-coded. • Double bagging is required only if leakage is possible. **Labels:**

[63] 29 CFR 1910.1030

Criteria	VI. Infection Control Standards
	• A warning label is affixed to red-bagged regulated wastes, sharps containers, refrigerators/freezers containing blood or OPIM, containers used to store or transport blood or OPIM, and contaminated laundry or equipment for storage or transporting. • The international biohazard symbol with word "BIOHAZARD" *or* the words "Biohazardous Waste" label (fluorescent orange or red orange with contrasting lettering/symbols) is part of, or affixed to, the container. • Sharps containers are labeled with the words "Sharps Waste" or with the international biohazard symbol and the word "BIOHAZARD". • Individual containers of blood or OPIM are exempted from warning labels if placed inside a labeled secondary container for storage, transport, or disposal. • Alternative marking or color coding may be used to label contaminated laundry or specimen containers if the alternative marking permits employees on site to recognize that container requires compliance with Universal Precautions. **VI.B.3) (CE) Needlestick safety precautions are practiced on site.** **Needlestick Safety:**[64] • Contaminated sharps are discarded immediately. • Sharps containers are located close to the immediate area where sharps are used and are inaccessible to unauthorized persons. • Sharps are not bent, removed from a syringe, or recapped. Recapping, bending, or removing contaminated needles is permissible only if there is no feasible alternative or if such actions are required for a specific medical procedure. If recapping, bending, or removal is necessary, employers must ensure that workers use either a mechanical device or a one-handed technique. Needleless systems, needles with Engineered Sharps Injury Protection (ESIP) devices, and non-needle sharps are used (incl. in emergency kits), unless exemptions have been approved by Cal/OSHA.[65] • Security of portable containers in patient care areas is always maintained. • Any device capable of cutting or piercing (e.g. syringes, hypodermic needles, needleless devices, blades, broken glass, slides, vials) are placed in a closable, puncture-resistant, labeled,

[64] See the OSHA Needlestick Safety Frequently Asked Questions, available at: https://www.osha.gov/needlesticks/needlefaq.html, and the OSHA Standards for Bloodborne Pathogens, available at: https://www.hercenter.org/rmw/osha-bps.php.

[65] 8 CCR 5193

Criteria	VI. Infection Control Standards
	leak-proof container. If these requirements are met, containers made of various materials (e.g., cardboard, plastic) are acceptable. • Containers are not overfilled past the manufacturer's designated fill line, or more than ¾ full. • Supply of containers on hand is adequate to ensure routine change-out when filled. **VI.B.4) All sharp injury incidents are documented.** **Sharps Injury Documentation:**[66] • Site has a method in place to document sharps injuries. • The Sharps Injury Log must contain, at a minimum, information about the injury, the type and brand of device involved in the injury (if known), the department or work area where the exposure occurred, and an explanation of how the incident occurred. • The incident must be recorded in the log within 14 business days of the date the incident is reported to the employer and maintained in such a manner to protect the confidentiality of the injured employee (e.g., removal of personal identifiers) and follow-up care is documented within 14 days of injury incident. • Sites with 10 or fewer employees are exempt from OSHA recordkeeping requirements and are exempt from recording and maintaining a Sharps Injury Log, however, it is recommended to have a method in place to document sharps injuries regardless of the number of employees. **Regulated Waste Storage:** Regulated wastes include: ○ **Biohazardous wastes**, e.g., laboratory wastes, human specimens/tissue, blood/contaminated materials "known" to be infected with highly communicable diseases for humans and/or that require isolation. ○ **Medical wastes**, e.g., liquid/semi-liquid blood or OPIM, items caked with dry blood or OPIM and capable of releasing materials during handling, and contaminated sharps. **VI.B.5) Biohazardous (non-sharp) wastes are contained separate from other trash/waste.**

[66] See 8 CCR 5193, and the National Institute for Occupational Safety and Health's guidance on Preventing Needlesticks and Sharps Injuries, available at: https://www.cdc.gov/niosh/topics/bbp/sharps.html.

Criteria	VI. Infection Control Standards
	VI.B.6) Storage areas for regulated medical wastes are maintained secure and inaccessible to unauthorized persons.[67] • Regulated waste is contained separately from other wastes (e.g., contaminated wastes)* and placed in red biohazardous bags with Biohazard label and stored in a closed container that is not accessible to unauthorized persons. • If stored outside the office, a lock secures the entry door, gate or receptacle lid, and posted warning sign(s) in English and Spanish are visible for 25-feet: "CAUTION-BIOHAZARDOUS WASTE STORAGE AREA- UNAUTHORIZED PERSONS KEEP OUT" and CUIDADO-ZONA DE RESIDUOUS-BIOLOGICOS PELIGOROS-PROHIBIDA LE ENTRADA A PERSONAS NO AUTHORIZADAS". See HSC Sections 117915-117946, 49 CFR, Section 173.6; Core Infection Prevention and Control Practices -Centers for Disease Control and Prevention (CDC) The Healthcare Infection Control Advisory Committee (HICPAC), 2016. **VI.B.7) Contaminated laundry is laundered at the workplace or by a commercial laundry service.** **<u>Contaminated Laundry</u>:** • Contaminated laundry (soiled with blood/OPIM) is laundered by a commercial laundry service, or a washer and dryer on site. • Contaminated laundry should not contain sharps, and when transported, should have the appropriate warning label. • Manufacturer's guidelines are followed to decontaminate and launder reusable protective clothing. • Ensure that laundry areas have handwashing facilities and products and appropriate PPE available for staff. • Laundry requirements are "not applicable" if only disposable patient gowns and PPE are used on site.

[67] HSC 117600-118360, 29 CFR 1910.1030, CDC Guidelines for Isolating Precautions: Preventing Transmission of Infection Agents in Healthcare Settings, available at: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html.

Criteria	VI. Infection Control Standards
	VI.B.8) Transportation of regulated medical wastes is only by a registered hazardous waste hauler or to a central location of accumulation in limited quantities (up to 35.2 pounds). **Medical Waste Disposal:** California adopted statutes into HSC affecting medical waste transporters in October 1993.[68] • Only medical waste transporters listed with CDPH can transport medical waste. • All medical waste transporters must carry paperwork issued by CDPH in each vehicle while transporting medical waste. • Medical wastes are hauled to a permitted offsite medical waste treatment facility, transfer station, or other registered generator by a registered hazardous waste transporter. • Limited-quantity exemption is not required for Small Quantity Generator (up to 35.2 pounds). However, a medical waste-tracking document that includes the name of the person transporting, number of waste containers (e.g., three sharps containers, or five biohazard bags), types of medical wastes, and date of transportation, is kept a minimum of 3 years for large waste generators and 2 years for small generators. For the CDPH list of current medical waste transporters, visit: https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/EMB/MedicalWaste/Haulist_012921.pdf For information on the United States Postal Service mailability standards for medical waste (including sharps) refer to the Domestic Mail Manual, section 601.10.17: https://pe.usps.com/Archive/HTML/DMMArchive20100607/601.htm CDPH Medical Waste Management Program: https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx CDPH Medical Waste Management Program Transporter Checklist: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8660.pdf CDPH Medical Waste Transporter Annual Verification: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8668.pdf

[68] HSC 117600-11836

Criteria	VI. Infection Control Standards
	CDPH Medical Waste Transfer Stations and Offsite Treatment Facilities: https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Transfer-and-Treatment.aspx CDPH Medical Waste Transporters Data Submission Protocol: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8666.pdf Department of Toxic Substances Control-Managing Hazardous Waste Transporters Registration https://dtsc.ca.gov/transporters/ ***Note:** Contaminated wastes include materials soiled with blood during their use but are not within the scope of regulated wastes. Contaminated waste items need not be disposed as regulated waste in labeled red bags but can be discarded as solid waste in regular trash receptacle.
C. Contaminated surfaces are decontaminated according to Cal-OSHA standards. **RN/NP/CNM/LM/MD/PA**	**Deficiencies:** All deficiencies related to Infection Control must be addressed in a corrective action plan (CAP). **VI.C.1) Equipment and work surfaces are appropriately cleaned and decontaminated after contact with blood or other potentially infectious material.** **Routine Decontamination:** ○ Contaminated work surfaces are decontaminated with an appropriate disinfectant.[69] ○ Written "housekeeping" schedules have been established and are followed for regular routine daily cleaning. ○ Staff can identify cleaning and disinfection of surfaces and equipment, the disinfectant used and responsible personnel in between patients use. **VI.C.2) Routine cleaning and decontamination of equipment/work surfaces is completed according to site-specific written schedule.** **The written schedule for cleaning and decontamination of the work site as follows:** ○ **Area cleaned/decontaminated**

[69] 29 CFR 1910.1030

Criteria	VI. Infection Control Standards
	○ **Frequency of cleaning/decontamination** ○ **Employee responsible for determining and implementing the written schedule** All equipment and environmental and work surfaces shall be cleaned and decontaminated after contact with blood or OPIM no later than at the end of the shift. Cleaning and decontamination of equipment and work surfaces is required more often as specified below: ○ Location within the facility ○ Type of surface or equipment to be treated ○ Type of soil or contamination present ○ Tasks or procedures being performed in the area Contaminated work surfaces shall be cleaned and decontaminated with an appropriate disinfectant immediately or as soon as feasible when: ○ Surfaces become overtly contaminated. ○ There is a spill of blood or OPIM. ○ Procedures are completed. ○ At the end of the work shift if the surface may have become contaminated since the last cleaning. **Spill Procedure:** Personnel can identify procedures for prompt decontamination of blood/body fluid spills, the disinfectant used, and the responsible person(s). **Disinfectant solutions used on site are:** **VI.C.3) Approved by the Environmental Protection Agency (EPA).** **VI.C.4) Effective in killing HIV/HBV/TB.** **VI.C.5) Follow manufacturer instructions.** **Disinfectant Products:** ○ Products used for decontamination have a current EPA-approved status. ○ Effectiveness in killing HIV/HBV/TB is stated on the manufacturer's product label. ○ Decontamination products are used according to manufacturer's guidelines for decontamination and contact times.

Criteria	VI. Infection Control Standards
	<u>10% Bleach Solution</u>: ○ 10% bleach solution that is EPA registered and effective against TB, is changed/reconstituted ***every*** 24 hours (due to instability of bleach once mixed with water). ○ Surface is cleaned prior to disinfecting (due to presence of organic matter (e.g., dirt, blood, excrement) inactivates active ingredient, sodium hypochlorite). ○ Surface is air-dried or allowed appropriate time (stated on label) before drying. ○ Manufacturer's directions, *specific* to every bleach product, are followed carefully. **<u>Note</u>:** "Contamination" means the presence or reasonably anticipated presence of blood or OPIM on any item or surface. "Decontamination" is the use of appropriate physical or chemical means to remove, inactivate or destroy bloodborne pathogens so that a surface or item is no longer capable of transmitting infectious particles and is rendered safe for handling, use or disposal.[70] Current EPA product lists and information is available from the EPA, Antimicrobial Division at (703) 305-1284, or at 29 CFR 1910.1030.
D. Reusable medical instruments are properly sterilized after each use. **RN/NP/CNM/LM/MD/PA**	**<u>Deficiencies</u>:** All deficiencies related to Infection Control must be addressed in a corrective action plan (CAP). **VI.D.1) Written site-specific policy/procedures or manufacturer's instructions for instrument/equipment sterilization are available to staff.** If site uses an autoclave or cold chemical solution to achieve sterilization and/or high level disinfection (HLD) of instruments/equipment, site shall have specific policy/procedures or manufacturer's instructions addressing instrument/equipment pre-treatment, cleaning and preparation, the management of chemical solutions, autoclave loading and operation, safety guidelines and precautions, and other required processes, which are available to staff to follow. **Staff adheres to site-specific policy and/or manufacturer/product label directions for the following procedures:** **VI.D.2) Cleaning reusable instruments/equipment prior to sterilization.** **<u>Cleaning Prior to Sterilization</u>:**

[70] 8 CCR 5193. Also see CalOSHA's Best Practices Approach for Reducing Bloodborne Pathogen Exposure, available at: https://www.dir.ca.gov/dosh/dosh_publications/BBPBest1.pdf.

Criteria	VI. Infection Control Standards
	• Prior to undergoing the sterilization process, soiled instruments/equipment are thoroughly cleaned using enzymatic detergent, rinsed, dried, and inspected for the presence of dried blood or other debris. **Cold chemical sterilization/high level disinfection:** **VI.D.3a) (CE) Staff demonstrate /verbalize necessary steps/process to ensure sterility and/or high-level disinfection of equipment.** • Personnel can demonstrate or verbally explain procedure(s) used for cleaning prior to sterilization, and to locate written directions on site. • Product efficacy tests (i.e. test strips) shall be performed according to manufacturer's guidelines. **Cold Chemical Sterilization/High Level disinfection:** • Product manufacturer's directions are strictly followed for instrument pre-soaking treatment, solution preparation, solution exposure procedures, safety precautions (e.g., room temperature, area ventilation), and post-sterilization processes. • Sterilization and or high-level disinfection exposure times and solution expiration date and time are available to staff. • Written procedures for cold sterilization and/or high-level disinfection is available on site to staff. **VI.D.3b) Confirmation from manufacturer item(s) is/are heat sensitive.** • Per CDC,[71] the use of liquid chemical germicides to sterilize instruments ("cold sterilization") are limited. Sterility is not verified or assured with cold chemical sterilization. The first choice is always heat sterilization. The CDC refers to heat sterilization as "the method of choice when sterilizing instruments and devices. If an item is heat sensitive, it is preferable to use a heat-stable alternative or disposable item". • The use of a liquid chemical sterilant should be restricted to reprocessing devices that are heat-sensitive and incompatible with other sterilization methods. All other items should be heat sterilized or disposable.

[71] See the CDC Guidelines for Disinfection and Sterilization, available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Also see the CDC's Guidelines on other sterilization methods, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/other-methods.html.

Criteria	VI. Infection Control Standards
	VI.D.3c) (CE) Appropriate PPE is available, exposure control plan, Material Safety Data Sheets (MSDS) and clean up instructions in the event of a cold chemical sterilant spill. Cold Chemical Sterilants Spillage: The OSHA Hazard Communication Standard requires manufacturers and importers of hazardous chemicals to develop MSDS for each chemical or mixture of chemicals.[72, 73] ○ Employers must have the data sheets for cold chemical sterilants readily available to employees who work with the products to which they could be exposed. ○ Staff should attend training classes in safety awareness about the use and exposure to cold chemical sterilants used on site. ○ Personnel are familiar with and can recognize signs and symptoms of exposure to cold chemical sterilants used on site. ○ Staff must be aware of the procedures for clean up in the event of spillage. ○ Staff can demonstrate or verbally explain procedure(s) used on site for chemical spill cleanup. ○ If personnel are unable to demonstrate or explain site-specific chemical spill cleanup procedures *and* cannot locate written chemical spill cleanup procedure instructions, site is considered deficient. ○ Cleanup procedures may vary from site to site depending on the cold chemical sterilants used. ○ The appropriate PPE for cold chemical sterilants clean up must be readily available. National Institute for Occupational Safety and Health (NIOSH) with the Centers for Disease Control and Prevention. Environmental Health and Safety guidelines for disinfectants and sterilization methods. MSDS for cold chemical sterilants. The American National Standard (ANSI)/Advancing Safety in Medical Technology (AAMI) ST58:2013. Control Methods and Work Practices: are in place to prevent or reduce exposure to the cold chemical sterilants. Cold chemical sterilants have toxic properties and are hazardous.

[72] 29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, and 1928.21.

[73] See CDC guidelines on sterilizing heat sensitive dental instruments, available at: https://oshareview.com/2013/10/cdc-guidelines-sterilizing-heat-sensitive-dental-instruments-dental-infection-control/. 29 CFR 1910.1030(d)(3)(i), 29 CFR 1910.1030(d)(3)(ii), 29 CFR 1910.1030(d)(4)(ii)(A), 29 CFR 1910.1030(d)(4)(iii)(B), 29 CFR 1910.132, 29 CFR 1910.134. See the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html.

Criteria	VI. Infection Control Standards
	• Cold chemical sterilants must be used strictly in accordance with the manufacturer's directions. Always consult the manufacturer for safety precautions and MSDS information. • The appropriate PPE must be used to avoid inhalation or skin contact exposure to during the cold chemical sterilization/high level disinfection process. Examples of cold chemical sterilants include: ○ Glutaraldehyde (Cidex) ○ Peracetic acid ○ Hydrogen peroxide-based solutions Glutaraldehyde is a common cold chemical sterilants. Exposure to glutaraldehyde can cause the following health effects: throat and lung irritation, breathing difficulty, nose irritation, nosebleed, burning eyes and conjunctivitis, rash, hives, headaches, and nausea. Exposure to glutaraldehyde may be prevented or reduced by using the following control methods and work practices: ○ Use local exhaust ventilation. ○ Keep glutaraldehyde baths under a fume hood where possible.[74] ○ Avoid skin contact (use appropriate PPE-gloves and aprons made of nitrile or butyl rubber wear goggles and face shields). ○ Use only enough sterilants to perform the required sterilization procedure. ○ Seal or cover all containers holding the sterilants. ○ Attend training classes. **Autoclave/Steam Sterilization:** **VI.D.4a) Staff demonstrate/verbalize necessary steps/process to ensure sterility.** • Autoclave manufacturer's directions are strictly followed for instrument pre-cleaning, machine loading, operation safety precautions, minimum time-temperature criteria, and post sterilization processes. • Written operating procedures for autoclave are available on site to staff. • Documentation of sterilization loads include date, time and duration of run cycle, temperature, steam pressure, and operator of each run.

[74] For more information on glutaraldehyde exposure and safety tips, refer to the CDC guidance, available at: https://www.cdc.gov/niosh/docs/2001-115/default.html.

Criteria	VI. Infection Control Standards
	• If instruments/equipment are transported off-site for sterilization, equipment handling, and transport procedures are available on site to staff. • Documentation of instruments and personnel transporting must be maintained. **VI.D.4 b) Autoclave maintenance per manufacturer's guidelines.** **Autoclave Maintenance:** Autoclave is maintained and serviced according to manufacturer's guidelines. Documentation of maintenance should include: o Mechanical problems o Inspection dates o Results/outcome of routine servicing o Calibration o Repairs, etc. **Note:** If the manufacturer's guidelines are not present on site, then the autoclave is serviced annually by a qualified technician. A dated sticker on the autoclave or a service receipt is acceptable documentation of appropriate maintenance. **VI.D.4c) (CE) Spore testing of autoclave/steam sterilizer with documented results (at least monthly).** **Spore Testing:** • Autoclave spore testing is performed *at least monthly*, unless otherwise stated in manufacturer's guidelines. • Documentation of biological spore testing includes: o Date o Results o Types of spore test used o Person performing/documenting test results • Written procedures for performing routine spore testing and for handling positive spore test results are available on site to staff. • For positive spore tests, the autoclave is removed from service immediately until inspection is completed and a negative retest occurs. Procedures include: o ***Report*** problem o ***Repair*** autoclave o ***Retrieve*** all instruments sterilized since last negative spore test

Criteria	VI. Infection Control Standards
	○ ***Re-test*** autoclave ○ ***Re-sterilize*** retrieved instruments • Biologic spore test products vary and are designed for use based on specific autoclave type. Biologic control testing challenges the autoclave sterilization cycle with live, highly resistant, nonpathogenic spores. If spores are killed during processing, it is assumed that all other microorganisms are also killed and that the autoclave load is sterile. **Note: Documentation of monthly spore testing must be maintained onsite even for sterilization that is performed offsite.** **VI.D.4.d) (CE) Management of positive mechanical, chemical, and biological indicators of the sterilization process.** **Autoclave/Steam Sterilization Mechanical, Chemical, and Biological Indicators:[75]** • Sterilization failure can occur for reasons such as slight variation in the resistance of the spores, improper use of the sterilizer, and laboratory contamination during the culture. • Per CDC, the autoclave/steam sterilization procedure should be monitored routinely by using a combination of: ○ Mechanical Indicator: monitor sterilization process with a daily assessment of cycle time and temperature by examining the temperature record chart and an assessment of pressure via the pressure gauge (e.g., graphs, gauges, printouts) ○ Chemical Indicator: are usually either heat-or chemical-sensitive inks that change color when one or more sterilization parameters (e.g., steam-time, temperature, and/or saturated steam; ETO-time, temperature, relative humidity and/or ETO concentration) are present. ○ Biological: spore test – an indicator to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items Staff should adhere to site-specific protocol and/or manufacturer/product label for management of positive indicator(s).

[75] See the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.

Criteria	VI. Infection Control Standards

	VI.D.4.e) Sterilized packages are labeled with sterilization date and load identification information.
	Package and storage of sterilized items:
	• Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination.
	• Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer).
	• Sterilized package labels include:
	  ○ Date of sterilization
	  ○ Load run identification information
	  ○ Initials of staff member
	  ○ General contents (e.g. suture set) each item in a sterile package need not be listed on the label if a master list of package contents is available elsewhere on site
	
	VI.D.4.f) Storage of sterilized packages.
	Storage of sterilized packages:[76]
	• Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer).
	• Maintenance of sterility is event related, not time related.
	• Sterilized items are considered sterile until use, unless an event causes contamination.
	• Sterilized items are not considered sterile if package is opened, wet/moist, discolored or damaged, and should be kept removed from sterile package storage area.
	• Site has a process for routine evaluation of sterilized packages.

[76] See the CDC Summary of Recommendations regarding Disinfection and Sterilization, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html, and the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.