Department of Health Care Services (DHCS)

Facility Site
Review Preparation Packet

If you have any questions or need help, please contact our Delegation Oversight Coordinators:

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Department of Health Care Services (DHCS)
Facility Site Review and Medical Records Review

Clinic Policies for Primary Care Provider Settings

Instructions:

All participating provider(s) sites are required to establish safety, member rights and general policies and procedures for their practice. Please review all sample policies and procedures in our educational packet and customize any or all of the policies and their respective attachments you wish to adopt based on your clinic's practice and processes. Please complete the *Approval date*, *Approved by*, *Effective Date*, and *Revision date* for each of the adopted policies. All providers and staff shall receive trainings/in-services on all clinic policies and procedures. Annual trainings/in-services are required for *Blood-Borne Pathogens Exposure Control*, *Biohazardous Waste Management* and *Infection Control/Standard/Universal Precautions*. All clinic policies and evidence of training shall be kept on site or made available upon request.

Facility Site Review Preparation Checklist

This communication applies to the Medicaid and Medicare-Medicaid Plan (MMP) programs.

Use this Facility Site Review (FSR) and Medical Record Review (MRR) preparation checklist to conduct an internal review of your practice to determine readiness for your upcoming FSR and/or MRR survey. You may reference the most current *California Department of Health Care Services (DHCS) Site Review and MRR Survey Standards*, the American Academy of Pediatrics (AAP), the U.S. Preventive Services Task Force (USPSTF), and other governing entity website links and health plan resources provided as embedded links (in blue) in the checklist below for more information. Reviewing the standards in the checklist (including directions/instructions, rules, regulation parameters, and/or indicators) prior to the FSR and MRR may improve and expedite the survey experience. Not all standards will be applicable to your location.

All new DHCS criteria are underlined. **All critical element criteria** are ***bolded and italicized***. Critical elements are related to potential adverse effects on patient health or safety and have a weighted score of two points. Each critical element found deficient during a full scope site survey, focused survey or monitoring visit shall be corrected by the provider within 10 business days from the survey date. All other criteria have a weighted score of one point and shall be corrected by the provider within 30 calendar days from the survey report date.

Please mark each criteria as "Yes" if your site complies with the requirement, or as "No" if your site does not comply. For each criteria marked as "No," you are encouraged to begin corrective actions prior to your actual survey. Before or at the start of your site visit, it would be useful for you to contact/inform your reviewer to discuss any non-compliant criteria.

We appreciate your cooperation and partnership in completing a successful review.

Facility Site				
Access/Safety		**Yes**	**No**	**Comments:**
1.	Clearly marked (blue) curb or sign designating disabled-parking space near accessible primary entrance			
2.	Pedestrian ramps have a level landing at the top and bottom of the ramp			
3.	Exit and exam room doorway openings allow for clear passage of a person in a wheelchair			
4.	Accessible passenger elevator or reasonable alternative for multilevel floor accommodation			
5.	Clear floor space for wheelchair in waiting area and exam room			
6.	Wheelchair accessible restroom facilities			
7.	Wheelchair accessible handwashing facilities or reasonable alternative			
8.	All patient areas including floor/carpet, walls, and furniture are neat, clean, and well-maintained			
9.	Restrooms are clean and contain appropriate sanitary supplies			
10.	There is evidence that site staff has received safety training and knows where to locate established Clinic Policies and Procedures on the following: a. Fire safety and prevention b. Emergency nonmedical procedures (e.g., earthquake/disaster, site evacuation, workplace violence)			
11.	Lighting is adequate in all areas to ensure safety			

	Access/Safety	Yes	No	Comments:
12.	***Exit doors and aisles are unobstructed and egress (escape) accessible*** https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.37			
13.	Exit doors are clearly marked with Exit signs			
14.	Clearly diagramed Evacuation Routes for emergencies are posted in a visible location at all elevators, stairs, and exits			
15.	Electrical cords and outlets are in good working condition			
16.	Fire-fighting equipment in accessible location https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.157			
17.	An employee alarm system utilized on site with back-up method to warn employees of a fire or other emergency shall be documented. For sites with 10 or fewer employees, direct verbal communication is acceptable and does not need does not need a back-up system https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.37			
18.	Personnel are trained in procedures/action plan to be carried out in case of a medical emergency on site. There is evidence that site staff has received training and knows where to locate established Clinic Policies and			
19.	Emergency equipment is stored together in easily accessible location and is ready to be used			
20.	Emergency phone number contact list is posted, dated, updated annually and as changes occur, and includes local emergency services (e.g., fire, police/sheriff, ambulance), emergency contacts (e.g., responsible managers/supervisors), and appropriate state, county, city, and local agencies (e.g., local poison control)			
21.	***Airway management equipment with sizes appropriate for patient population: oxygen delivery system, nasal cannula or mask, bulb syringe and Ambu bag***			
22.	***Emergency medicine for anaphylactic reaction management, opioid overdose, asthma, chest pain, and hypoglycemia: Epinephrine 1:1000 (injectable), and Benadryl 25 mg (oral) or Benadryl 50 mg/ml (injectable), Naloxone, chewable Aspirin 81 mg (at least four tablets), nitroglycerine spray/tablet, bronchodilator medication (solution for nebulizer or metered dose inhaler), glucose containing at least 15 grams, appropriate sizes of ESIP needles/syringes and alcohol wipes*** https://www.aafp.org/afp/2007/0601/p1679.html			
23.	Medication dosage chart for all medications included with emergency equipment (or other method for determining dosage) is kept with emergency medications			
24.	There is a process in place on site to document checking of emergency equipment/supplies for expiration and operating status at least monthly			
25.	There is a process in place on site to replace/re-stock emergency medication, equipment and supplies *immediately* after use			
26.	Medical equipment is clean			
27.	Written documentation demonstrates the appropriate maintenance of all medical equipment according to equipment manufacturer's guidelines			

Personnel		Yes	No	Comments:
1.	All required professional licenses and certifications issued from the appropriate licensing/certification agency are current			
2.	Notification is provided to each member that the Medical Doctor(s) (MD) is/are licensed and regulated by the Medical Board, and that the Physician Assistant(s) is/are licensed and regulated by the Physician Assistant Committee			
3.	Healthcare personnel wear identification badges/tags printed with name and title			
4.	Documentation of education/training for non-licensed medical personnel is maintained on site			
5.	***Only qualified/trained personnel retrieve, prepare, or administer medications***			
6.	Site has a procedure in place for confirming correct patient, medication/vaccine, dosage, and route prior to administration			
7.	Only qualified/trained personnel operate medical equipment			
8.	Scope of practice for non-physician medical practitioners (NPMPs) is clearly defined including the delegation of the supervision of Medical Assistants when supervising physician is off premises: a. Standardized procedures provided for nurse practitioners (NPs) and/or certified nurse midwives (CNMs) https://www.rn.ca.gov/pdfs/regulations/npr-b-03.pdf https://www.rn.ca.gov/pdfs/regulations/npr-b-20.pdf b. A Practice Agreement defines the scope of services provided by physician assistants (PAs) and supervisory guidelines define the method of supervision by the supervising physician http://www.pab.ca.gov https://www.pab.ca.gov/forms_pubs/sb697faqs.pdf c. 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. Frequency of review to identify changes in scope of service shall be specified in writing.			
9.	NPMPs are supervised according to established standards: a. The ratio of supervising physician to the number of NPMPs does not exceed established ratios in any combination at any given time/shift in any of the locations: • 1:4 NPs • 1:4 CNMs • 1:4 PAs (per shift in any given location) b. 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 c. There is evidence of NPMP supervision.			
10.	There is evidence that site staff has received training and knows where to locate established Clinic Policies and Procedures on the following: a. Infection Control/Universal Precautions (annually) b. Bloodborne Pathogens Exposure Prevention (annually) c. Biohazardous Waste Handling (annually) d. Patient Confidentiality e. Informed Consent, including Human Sterilization f. Prior Authorization Requests			

Personnel		Yes	No	Comments:
	g. Grievance/Complaint Procedure h. Child/Elder/Domestic Violence Abuse i. Sensitive Services/Minors' Rights j. Health Plan Referral Process/Procedures/Resources k. Cultural and Linguistics https://www.health.pa.gov/topics/Documents/Health%20Equity/CLAS%20Standards%20FactSheet.pdf l. Disability Rights and Provider Obligations: a. Post notice of consumers civil rights; b. For sites with 15 or more employees, have civil rights procedure and an employee designated to coordinate compliance; and c. Information on physical access and reasonable accommodations https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factshs/504.pdf			

Office Management		Yes	No	Comments:
1.	Clinic office hours are posted or readily available upon request			
2.	Provider office hour schedules are available to staff			
3.	Arrangement/schedule for after-hours, on-call, supervisory back-up physician coverage is available to site staff			
4.	Contact information for off-site physician(s) is available at all times during office hours			
5.	Routine, urgent, and after-hours emergency care instructions/telephone information is made available to patients			
6.	Appropriate personnel handle emergent, urgent, and medical advice telephone calls			
7.	Telephone answering machine, voice mail system or answering service is used whenever office staff does not directly answer phone calls			
8.	Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated			
9.	Appointments are scheduled according to patients' stated clinical needs within the timeliness standards established for plan members			
10.	Patients are notified of scheduled routine and/or preventive screening appointments			
11.	There is a process in place verifying follow-up on missed and canceled appointments			
12.	Interpreter services are made available 24 hours in identified threshold languages specified for location of site https://www.federalregister.gov/documents/2003/08/08/03-20179/guidance-to- federal-financial-assistance-recipients-regarding-title-vi-prohibition-against- national			
13.	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. A written policy shall be in place.			
14.	Office practice procedures allow timely provision and tracking of: a. Processing internal and external referrals, consultant reports, and diagnostic test results.			

Office Management		Yes	No	Comments:
	b. ***Physician review and follow-up of referral/consultation reports and diagnostic test results.***			
15.	Phone number(s) for filing grievances/complaints are located on site			
16.	Complaint forms and a copy of the grievance procedure are available onsite.			
17.	Medical records are readily retrievable for scheduled patient encounters.			
18.	Medical documents are filed in a timely manner to ensure availability for patient			
19.	Exam rooms and dressing areas safeguard patients' right to privacy.			
20.	Procedures are followed to maintain the confidentiality of personal patient information (sign-in sheets with only one patient identifier, signed confidentiality agreement from after-hours cleaning crew, etc.).			
21.	Medical record release procedures are compliant with state and federal guidelines.			
22.	Storage and transmittal of medical records preserves confidentiality and security.			
23.	Medical records are retained for a minimum of 10 years			

Clinical Services		Yes	No	Comments:
1.	Drugs are stored in specifically designated cupboards, cabinets, closets, or drawers			
2.	Prescription, drug samples, over-the-counter drugs, hypodermic needles/syringes, all medical sharp instruments, hazardous substances (disinfectant solutions/wipes), and prescription pads are securely stored in a lockable space (cabinet or room) within the office/clinic			
3.	Controlled drugs are stored in a locked cabinet accessible only to authorized personnel.			
4.	A dose-by-dose controlled substance distribution log is maintained.			
5.	Written site-specific policy/procedure for dispensing of sample drugs are available on site. (A list of dispensed and administered medications shall be present on site).			
6.	Drugs are prepared in a clean area or designated clean area if prepared in a multipurpose room.			
7.	Drugs for external use are stored separately from drugs for internal use.			
8.	Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.			
9.	Refrigerator thermometer temperature is 36º to 46º Fahrenheit or 2º to 8º Centigrade (at time of site visit).			
10.	Freezer thermometer temperature is 5º Fahrenheit, or -15º Centigrade or lower (at time of site visit).			
11.	Site utilizes drugs/vaccine storage units that are able to maintain required temperature. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf			
12.	Daily temperature readings of drugs/vaccines refrigerator and freezer are documented. CDC recommends use of a continuous temperature monitoring device or digital data loggers (DDLs). Back-up DDL(s) for each transport storage unit shall be readily available for emergency vaccine transport or when primary DDL(s) is sent in for calibration.			

Clinical Services		Yes	No	Comments:
13.	Has a written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer			
14.	Drugs and vaccines are stored separately from test reagents, germicides, disinfectants, and other household substances.			
15.	Hazardous substances are appropriately labeled			
16.	Site has method(s) in place for drug and hazardous substance disposal			
17.	There are no expired drugs on site.			
18.	Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas			
19.	All stored and dispensed prescription drugs are appropriately labeled			
20.	***Only lawfully authorized persons dispense drugs to patients***			
21.	***Drugs and vaccines are prepared and drawn only prior to administration***			
22.	Current *Vaccine Information Sheets (VIS)* for distribution to patients are present on site.			
23.	If there is a pharmacy on site, it is licensed by the California State Board of Pharmacy			
24.	Site utilizes California Immunization Registry (CAIR)			
25.	Laboratory test procedures are performed according to current site-specific CLIA certificate			
26.	Testing personnel performing clinical lab procedures have been trained			
27.	Lab supplies (vacutainers, vacutainer tubes, culture swabs, test solutions) are inaccessible to unauthorized persons.			
28.	Lab test supplies are not expired.			
29.	Site has a procedure to check expiration date and a method to dispose of expired lab test supplies.			
30.	Site has current California Radiologic Health Branch Inspection Report (in the last 5 years) and proof of registration if there is radiological equipment on site https://www.cdph.ca.gov/rhb			
31.	The following documents are posted on site: a. Current copy of *Title 17* with a posted notice about availability of *Title 17* and its location b. Radiation Safety Operating Procedures posted in highly visible location c. Notice to Employees Poster posted in highly visible location d. Caution, X-ray sign posted on or next to door of each room that has X-ray equipment e. Physician supervisor/operator certificate posted and within current expiration date f. Technologist certificate posted and within current expiration date			
32.	The following radiological protective equipment is present on site: a. Operator protection devices: radiological equipment operator must use lead apron or lead shield			

Clinical Services		Yes	No	Comments:
	b. Gonadal shield (0.5 mm or greater lead equivalent): for patient procedures in which gonads are in direct beam			

Preventive Services		Yes	No	Comments:
1.	Examination equipment appropriate for primary care services is available on site.			
2.	Exam tables and lights are in good repair.			
3.	Stethoscope and sphygmomanometer with various size cuffs appropriate for patient population (e.g., small, regular, large/obese/thigh)			
4.	Thermometer with a numeric reading			
5.	Basic exam equipment: percussion hammer, tongue blades, patient gowns			
6.	Scales: standing balance beam and infant scales			
7.	Measuring devices for stature (height/length) measurement and head circumference measurement			
8.	Eye charts (literate and illiterate) and occluder for vision testing (proper use of heel line) are available on site. 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. The AAP recommended eye • LEA symbols (children 3 to 5 years old) • HOTV chart (children 3 to 5 years old) • Sloan letters (preferred) or Snellen letters (children over 5 years old and adults)			
9.	Ophthalmoscope			
10.	Otoscope with adult and pediatric ear speculums			
11.	A pure tone, air conduction audiometer is in a quiet location for testing.			
12.	Health education materials and plan-specific resource information are: a. Readily accessible on site or are made available upon request b. Applicable to the practice and population served on site c. Available in threshold languages identified for county and/or area of site location			

Infection Control		Yes	No	Comments:
1.	Soap or antiseptic hand cleaner and running water are available in exam and/or treatment areas for hand washing.			
2.	A waste disposal container is available in exam rooms, procedure/treatment rooms, and restrooms.			
3.	Site has procedure for effectively isolating infectious patients with potential communicable conditions.			
4.	***Personal protective equipment for standard precautions is readily available for staff use (e.g., gloves, water-repelling gowns, face/eye***			

Infection Control		Yes	No	Comments:
5.	***Blood, other potentially infectious materials, and regulated wastes are placed in appropriate leak-proof, labeled containers for collection, handling, processing, storage, transport, or shipping.***			
6.	***Needle-stick safety precautions are practiced on site. (Only safety needles and wall-mounted/secured sharps containers are used on site; Sharps containers are not overfilled; etc.)***			
7.	All sharp injury incidents are documented.			
8.	Contaminated laundry is laundered at the workplace or by a commercial laundry service.			
9.	Biohazardous (non-sharp) wastes are contained separate from other trash/waste.			
10.	Storage areas for regulated medical wastes are maintained secure and inaccessible to unauthorized persons.			
11.	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).			
12.	Equipment and work surfaces are appropriately cleaned and decontaminated after contact with blood or other potentially infectious material.			
13.	Routine cleaning and decontamination of equipment/work surfaces is completed according to site-specific written schedule.			
14.	Disinfectant solutions used on site: a. Are approved by the Environmental Protection Agency (EPA). b. Are effective in killing HIV/HBV/TB. c. Follow manufacturer instructions.			
15.	Written site-specific policy/procedures or manufacturer's instructions for instrument/equipment sterilization are available to staff.			
16.	Staff adheres to site-specific policy and/or manufacturer/product label directions for the following procedures: a. Cleaning reusable instruments/equipment prior to sterilization			
17.	Cold chemical sterilization/high level disinfection: a. Confirmation from manufacturer item(s) is/are heat-sensitive b. ***Staff demonstration /verbalize necessary steps/process to sterility and/or high-level disinfection ensure sterility of*** c. ***Appropriate PPE is available, exposure control plan and clean up instructions in the event of a cold chemical sterilant spill — so l u ti o n ' s M SDS shall be available on site*** https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html			
18.	Autoclave/steam sterilization: a. Staff demonstration/verbalize necessary steps/process to ensure sterility Documentation of sterilization loads include date, time, and duration of run cycle, temperature, steam pressure, and operator of each run. b. Autoclave maintenance per manufacturer's guidelines c. ***Spore testing of autoclave/steam sterilizer with documented results (at least monthly)*** d. ***Management of positive mechanical, chemical, and/or biological indicators of the sterilization process***			

Infection Control		Yes	No	Comments:
19.	Sterilized packages are labeled with sterilization date and load identification information			
20.	Storage areas for sterilized packages are clean, dry, and separated from non- sterile items by a functional barrier. Site has a process for routine evaluation of sterilized packages.			

California Department of Health service
CRITICAL ELEMENT STANDARDS

* Critical Element deficiencies must be corrected within 14 days (10 business days) of the onsite audit. This form is created to allow you to get a head start on meeting the standards.

STANDARD	STANDARD NOT MET IF:	RECOMMENDATIONS
ALL exit doors must be cleared of any debris or blockage that would hamper evacuation	Exit doors and aisles are obstructed and escape is impeding or not accessible	Make sure all exit doors are cleared and accessible.
Oxygen delivery system, oral airways, nasal cannulas and/or masks, and an ambu bag are available onsite.	All elements must be in place. If any item is not available, the standard will be marked as not met.	Make sure the Oxygen tank is at least ¾ full. Have available oral airways in various sizes, Ambu Bag, and Cannulas and/or masks to meet the patient population.
Emergency medicine for anaphylactic reaction management, opioid overdose, chest pain, asthma, and hypoglycemia. Epinephrine 1mg/ml (injectable) and Diphenhydramine (Benadryl) 25 mg (oral) or Diphenhydramine (Benadryl) 50 mg/ml (injectable), Naloxone, chewable Aspirin 81 mg, Nitroglycerine spray/tablet, bronchodilator medication (solution for nebulizer or metered dose inhaler), and glucose (any type of glucose containing at least 15 grams). Appropriate sizes of ESIP needles/syringes and alcohol wipes.	One or more of the emergency medicines and/or supplies are missing.	Make sure that Epinephrine 1mg/ml (injectable) and Diphenhydramine (Benadryl) 25 mg (oral) or Diphenhydramine (Benadryl) 50 mg/ml (injectable), Naloxone, chewable Aspirin 81 mg, Nitroglycerine spray/tablet, bronchodilator medication (solution for nebulizer or metered dose inhaler), and glucose (any type of glucose containing at least 15 grams), appropriate sizes of ESIP needles/syringes, and alcohol wipes are readily available onsite.
Only trained, qualified personnel retrieve, prepare and/or administer medications.	No evidence that qualified /trained personnel retrieve, prepare or administer medications. Non-licensed personnel administer medications without the proper supervision or oversight by licensed personnel.	Medical Assistants cannot administer medications independently. Prior to administration, the dosage and the medication must be verified by licensed personnel.
A procedure is in place to document physician review and follow up on referrals, consultations, and diagnostic tests.	There is no documented evidence that a physician reviewed or followed up on referrals, consultations, and diagnostics tests	Make sure all reports and tests are marked as reviewed and appropriate follow up is in place.
Only physicians, licensed mid-level practitioners, and licensed nurses will dispense medications to patients.	Medications are being dispensed to patients by other than lawfully authorized persons.	Make sure there is a process in place to ensure that only licensed personnel dispense medications to patients.
Drugs and Vaccines are prepared and drawn only prior to administration.	Minimum of 5 administration rights not met. There are more than 10 prefilled syringes onsite, and doses are not administered as soon as possible by the same person who filled the syringes.	Make sure 5 administration rights (right person, right medication, right dose, right route, right time) are done prior to administration. ACIP discourages the routine practice of providers' prefilling syringes. 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. The doses should be administered as soon as possible after filling, by the same person who filled the syringes.
Blood borne Pathogens Protection equipment has been obtained and is readily available for use by office personnel. This includes fluid repelling gloves, clothing barrier, goggles and mark or face shield with mask.	Personal Protection Equipment (PPE) is not available to staff	Make sure that PPE (Gown/ Goggles or Eyewear/ Mask/ Gloves) are available to staff. Recommend at least 2 sets.
Blood, other potentially infectious material and regulated wastes are placed in appropriate leak proof, labeled containers for collection, handling, processing, storage, transport or shipping.	Blood, other potentially infectious materials, and regulated wastes are placed in leak proof labeled containers.	Make sure that all biohazardous materials are in appropriate containers and secured and there is a process in place for disposal.
Needle stick safety precautions are practiced on site and sharps containers are secured and not accessible to unauthorized persons.	Needle stick precautions are not implemented. Sharps containers are unsecured and accessible to unauthorized persons.	Make sure that all needles used for patient care are safety needles. Portable sharp containers are secured at all times.
Staff demonstrate /verbalize necessary steps/process to ensure sterility and/or high-level disinfection of equipment	Staff unable to demonstrate or verbalize steps/process to sterilization of equipment. There are no written procedures for cold sterilization and/or high-level disinfection available on site for staff.	Make sure staff can demonstrate or verbally explain procedure(s) used for cleaning prior to sterilization, and to locate written directions on site.
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 Sterilant Spillage	No PPE available for cold chemical sterilant spill and cold sterilization are not performed in well ventilated area. Staff unable to demonstrate/ explain site specific chemical spill cleanup procedures and cannot locate written chemical spill cleanup procedure instructions.	Make sure appropriate PPE for cold chemical sterilant cleanup is readily available. Make sure cold sterilization are done in well ventilated area. Make sure staff can demonstrate/explain procedure(s) used for chemical spill. Make sure there is Material Safety Data Sheet (MSDS) and cleanup procedure/instructions on the cold chemical sterilant used.
Monthly spore testing of the autoclave/steam sterilized has been implemented.	Monthly Spore testing of the autoclave/steam sterilized has not been performed	Make sure that documentation is available to demonstrate that monthly spore testing has been performed.
Management of positive mechanical, chemical, and biological indicators of the sterilization process.	Sterilization procedures are not monitored routinely by using a combination of mechanical, chemical, and biological indicators. A written Policy and Procedure are not readily available onsite.	Make sure autoclave/steam sterilization procedure are monitored routinely by using combination of mechanical indicator (temperature record chart and pressure gauge), chemical indicator (heat/chemical sensitive ink that change color when sterilization parameters are present), and biological indicators (spore test). Make sure there is a written Policy and Procedure readily available onsite.

OSHA® FactSheet

Emergency Exit Routes

How would you escape from your workplace in an emergency? Do you know where all the exits are in case your first choice is too crowded? Are you sure the doors will be unlocked and that the exit access, such as a hallway, will not be blocked during a fire, explosion, or other crisis? Knowing the answers to these questions could keep you safe during an emergency.

What is an *exit route*?

An *exit route* is a continuous and unobstructed path of exit travel from any point within a workplace to a place of safety. An *exit route* consists of three parts:

- **Exit access** – portion of an *exit route* that leads to an exit.
- **Exit** – portion of an *exit route* that is generally separated from other areas to provide a protected way of travel to the *exit discharge*.
- **Exit discharge** – part of the *exit route* that leads directly outside or to a street, walkway, refuge area, public way, or open space with access to the outside.

How many *exit routes* must a workplace have?

Normally, a workplace must have at least two exit routes to permit prompt evacuation of employees and other building occupants during an emergency. More than two exits are required, however, if the number of employees, size of the building, or arrangement of the workplace will not allow employees to evacuate safely. *Exit routes* must be located as far away as practical from each other in case one is blocked by fire or smoke.

Exception: If the number of employees, the size of the building, its occupancy, or the arrangement of the workplace allows all employees to evacuate safely during an emergency, one *exit route* is permitted.

What are some other design and construction requirements for exit routes?

- *Exit routes* must be permanent parts of the workplace.
- *Exit discharges* must lead directly outside or to a street, walkway, refuge area, public way, or open space with access to the outside. These *exit discharge* areas must be large enough to accommodate the building occupants likely to use the *exit route*.
- *Exit stairs* that continue beyond the level on which the *exit discharge* is located must be interrupted at that level by doors, partitions, or other effective means that clearly indicate the direction of travel leading to the *exit discharge*.
- *Exit route* doors must be unlocked from the inside. They must be free of devices or alarms that could restrict use of the *exit route* if the device or alarm fails.
- Side-hinged exit doors must be used to connect rooms to *exit routes*. These doors must swing out in the direction of exit travel if the room is to be occupied by more than 50 people or if the room is a high-hazard area.
- *Exit routes* must support the maximum permitted occupant load for each floor served, and the capacity of an *exit route* may not decrease in the direction of *exit route* travel to the *exit discharge*.
- Ceilings of *exit routes* must be at least 7 feet, 6 inches high.
- An exit access must be at least 28 inches wide at all points. Where there is only one exit access leading to an exit or exit discharge, the width of the exit and exit discharge must be at least equal to the width of the exit access. Objects that project into the exit must not reduce its width.
- Outdoor *exit routes* are permitted but must meet the minimum height and width requirement for indoor *exit routes* and must
  - have guardrails to protect unenclosed sides if a fall hazard exists;
  - be covered if snow or ice is likely to accumulate, unless the employer can demonstrate accumulations will be removed before a slipping hazard exists;
  - be reasonably straight and have smooth, solid, substantially level walkways;and
  - not have a dead-end longer than 20 feet.

What are the requirements for exits?

- *Exits* must be separated by fire resistant materials—that is, one-hour fire-resistance rating if the exit connects three or fewer stories and two-hour fire-resistance rating if the exit connects more than three floors.
- *Exits* are permitted to have only those openings necessary to allow access to the *exit* from occupied areas of the workplace or to the *exit discharge*. Openings must be protected by a self-closing, approved *fire door* that remains closed or automatically closes in an emergency.

What are the maintenance, safeguarding, and operational features for exit routes?

OSHA standards require employers to do the following:

- Keep e*xit routes* free of explosive or highly flammable furnishings and other decorations.
- Arrange *exit routes* so employees will not have to travel toward a high-hazard area unless the path of travel is effectively shielded from the high-hazard area.
- Ensure that e*xit routes* are unobstructed such as by materials, equipment, locked doors, or dead-end corridors.
- Ensure that safeguards designed to protect employees during an emergency remain in good working order.
- Provide lighting for *exit routes* adequate for employees with normal vision.
- Keep *exit route* doors free of decorations or signs that obscure the visibility of *exit route doors*.
- Post signs along the *exit access* indicating the direction of travel to the nearest *exit* and *exit discharge* if that direction is not immediately apparent. Also, the line-of-sight to an exit sign must be clearly visible at all times.
- Mark doors or passages along an *exit access* that could be mistaken for an *exit* "Not an Exit" or with a sign identifying its use (such as "Closet").
- Install "EXIT" signs in plainly legible letters.
- Renew fire-retardant paints or solutions often enough to maintain their fire-retardant properties.
- Maintain e*xit routes* during construction, repairs, or alterations.
- Provide an emergency alarm system to alert employees, unless employees can promptly see or smell a fire or other hazard in time to provide adequate warning to them.

Are employers required to have emergency action plans?

If you have *10 or fewer employees*, you may communicate your plan orally. If you have *more than 10 employees*, however, your plan must be written, kept in the workplace, and available for employee review. Although employers are required to have an emergency action plan (EAP) only when the applicable OSHA standard requires it, OSHA strongly recommends that all employers have an EAP. Here are the OSHA standards that require EAPs:

- Process Safety Management of Highly Hazardous Chemicals - 1910.119
- Fixed Extinguishing Systems, General - 1910.160
- Fire Detection Systems, 1910.164
- Grain Handling - 1910.272
- Ethylene Oxide - 1910.1047
- Methylenedianiline - 1910.1050
- 1,3-Butadiene - 1910.1051

What are the minimum elements of an emergency action plan?

- Procedures for reporting fires and other emergencies.
- Procedures for emergency evacuation, including the type of evacuation and *exit route* assignments.
- Procedures for employees who stay behind to continue critical plant operations.
- Procedures to account for all employees after evacuation.
- Procedures for employees performing rescue or medical duties.
- Name or job title of employees to contact for detailed plan information.
- Alarm system to alert workers.

In addition, you must designate and train employees to assist in a safe and orderly evacuation of other employees. You must also review the emergency action plan with each employee covered when the following occur:

- Plan is developed or an employee is assigned initially to a job.
- Employee's responsibilities under the plan changes.
- Plan is changed.

Must all employers have fire prevention plans?

If you have *10 or fewer employees*, you may communicate your plan orally. If you have *more than 10 employees*, however, your plan must be written, kept in the workplace, and available for employee review. Although employers are only required to have a fire prevention plan (FPP) when the applicable OSHA standard requires it, OSHA strongly recommends that all employers have a FPP. The following OSHA standards require fire prevention plans:

- Ethylene Oxide - 1910.1047
- Methylenedianiline - 1910.1050
- 1,3-Butadiene - 1910.1051

Here are the minimum provisions of a fire prevention plan:

- List of all major fire hazards, proper handling and storage procedures for hazardous materials, potential ignition sources and their control, and the type of fire protection equipment necessary to control each major hazard.
- Procedures to control accumulations of flammable and combustible waste materials.
- Procedures for regular maintenance of safeguards installed on heat-producing equipment to prevent the accidental ignition of combustible materials.
- Name or job title of employees responsible for maintaining equipment to prevent or control sources of ignition or fires.
- Name or job title of employees responsible for the control of fuel source hazards.

In addition, when you assign employees to a job, you must inform them of any fire hazards they may be exposed to. You must also review with each employee those parts of the fire prevention plan necessary for self-protection.

How can I get more information on *exit route* safety?

For more detail on exit routes and related standards see *Exit Routes, Emergency Action Plans, and Fire Prevention Plans* in *Title 29 of the Code of Federal Regulations* (*CFR*) 1910.33-39; and OSHA Directive CPL 2-1.037, *Compliance Policy for Emergency Action Plans and Fire Prevention Plans*. In addition, employers who comply with the exit route provisions of the National Fire Protection Association's 101-2009, *Life Safety Code*, or the exit provisions of the International Fire Code, 2009, will be considered in compliance with the OSHA requirements for exit routes.

Workers' Rights

Workers have the right to:

- Working conditions that do not pose a risk of serious harm.
- Receive information and training (in a language and vocabulary the worker understands) about workplace hazards, methods to prevent them, and the OSHA standards that apply to their workplace.
- Review records of work-related injuries and illnesses.
- File a complaint asking OSHA to inspect their workplace if they believe there is a serious hazard or that their employer is not following OSHA's rules. OSHA will keep all identities confidential.
- Exercise their rights under the law without retaliation, including reporting an injury or raising health and safety concerns with their employer or OSHA. If a worker has been retaliated against for using their rights, they must file a complaint with OSHA as soon as possible, but no later than 30 days.

For additional information, see OSHA's Workers page (www.osha.gov/workers).

How to Contact OSHA

Under the Occupational Safety and Health Act of 1970, employers are responsible for providing safe and healthful workplaces for their employees. OSHA's role is to ensure these conditions for America's working men and women by setting and enforcing standards, and providing training, education and assistance. For more information, visit www.osha.gov or call OSHA at 1-800-321-OSHA (6742), TTY 1-877-889-5627.

This is one in a series of informational fact sheets highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999; teletypewriter (TTY) number: (877) 889-5627.

U.S. Department of Labor

OSHA® Occupational Safety and Health Administration

DSG FS-3943 03/2018

SITE EVACUATION PLAN

Instructions: Draw a diagram of your office with clearly marked exits and evacuation routes. Add important labels including where the evacuation plans are posted indicated by “You are here”, and other important information such as location(s) of fire extinguisher(s), primary and secondary evacuation routes indicated by arrows, etc. (see Legend below).

Legend:

OSHA FACT Sheet

Fire Safety in the Workplace

What should employers do to protect workers from fire hazards?

Employers should train workers about fire hazards in the workplace and about what to do in a fire emergency. If you want your workers to evacuate, you should train them on how to escape. If you expect your workers to use firefighting equipment, you should give them appropriate equipment and train them to use the equipment safely. (See Title 29 of the *Code of Federal Regulations* Part 1910 Subparts E and L; and Part 1926 Subparts C and F.)

What does OSHA require for emergency fire exits?

Every workplace must have enough exits suitably located to enable everyone to get out of the facility quickly. Considerations include the type of structure, the number of persons exposed, the fire protection available, the type of industry involved, and the height and type of construction of the building or structure. In addition, fire doors must not be blocked or locked when employees are inside. Delayed opening of fire doors, however, is permitted when an approved alarm system is integrated into the fire door design. Exit routes from buildings must be free of obstructions and properly marked with exit signs. See 29 *CFR* Part 1910.36 for details about all requirements.

Do employers have to provide portable fire extinguishers?

No. But if you do, you must establish an educational program to familiarize your workers with the *general principles* of fire extinguisher use. If you expect your workers to use portable fire extinguishers, you must provide *hands-on training* in using this equipment. For details, see 29 *CFR* Part 1910 Subpart L.

Must employers develop emergency action plans?

Not every employer is required to have an emergency action plan. OSHA standards that require such plans include the following:

- Process Safety Management of Highly Hazardous Chemicals, 1910.119
- Fixed Extinguishing Systems, General, 1910.160
- Fire Detection Systems, 1910.164
- Grain Handling, 1910.272
- Ethylene Oxide, 1910.1047
- Methylenedianiline, 1910.1050
- 1,3 Butadiene, 1910.1051

When required, employers must develop emergency action plans that:

- Describe the routes for workers to use and procedures to follow.
- Account for all evacuated employees.
- Remain available for employee review.
- Include procedures for evacuating disabled employees.
- Address evacuation of employees who stay behind to shut down critical plant equipment.
- Include preferred means of alerting employees to a fire emergency.
- Provide for an employee alarm system throughout the workplace.
- Require an alarm system that includes voice communication or sound signals such as bells, whistles, or horns.
- Make the evacuation signal known to employees.
- Ensure emergency training.
- Require employer review of the plan with new employees and with all employees whenever the plan is changed.

Must employers have a fire prevention plan?

OSHA standards that require fire prevention plans include the following:

- Ethylene Oxide, 1910.1047
- Methylenedianiline, 1910.1050
- 1,3 Butadiene, 1910.1051

Employers covered by these standards must implement plans to minimize the frequency of evacuations. All fire prevention plans must:

- Be available for employee review.

- Include housekeeping procedures for storage and cleanup of flammable materials and flammable waste.
- Address handling and packaging of flammable waste. (Recycling of flammable waste such as paper is encouraged.)
- Cover procedures for controlling workplace ignition sources such as smoking, welding, and burning.
- Provide for proper cleaning and maintenance of heat producing equipment such as burners, heat exchangers, boilers, ovens, stoves, and fryers and require storage of flammables away from this equipment.
- Inform workers of the potential fire hazards of their jobs and plan procedures.
- Require plan review with all new employees and with all employees whenever the plan is changed.

What are the rules for fixed extinguishing systems?

Fixed extinguishing systems throughout the workplace are among the most reliable fire fighting tools. These systems detect fires, sound an alarm, and send water to the fire and heat. To meet OSHA standards employers who have these systems must:

- Substitute (temporarily) a fire watch of trained employees to respond to fire emergencies when a fire suppression system is out of service.
- Ensure that the watch is included in the fire prevention plan and the emergency action plan.
- Post signs for systems that use agents (e.g., carbon dioxide, Halon 1211, etc.) posing a serious health hazard.

How can you get more information on safety and health?

OSHA has various publications, standards, technical assistance, and compliance tools to help you, and offers extensive assistance through workplace consultation, voluntary protection programs, strategic partnerships, alliances, state plans, grants, training, and education. OSHA's *Safety and Health Program Management Guidelines* (*Federal Register* 54:3904–3916, January 26, 1989) detail elements critical to the development of a successful safety and health management system. This and other information are available on OSHA's website.

- For one free copy of OSHA publications, send a self-addressed mailing label to OSHA Publications Office, 200 Constitution Avenue, N.W., N-3101, Washington, DC 20210; or send a request to our fax at (202) 693–2498, or call us at (202) 693–1888.
- To order OSHA publications online at **www.osha.gov**, go to **Publications** and follow the instructions for ordering.
- To file a complaint by phone, report an emergency, or get OSHA advice, assistance, or products, contact your nearest OSHA office under the U.S. Department of Labor listing in your phone book, or call toll-free at **(800) 321–OSHA (6742)**. The teletypewriter (TTY) number is (877) 889–5627.
- To file a complaint online or obtain more information on OSHA federal and state programs, visit OSHA's website.

This is one in a series of informational fact sheets highlighting OSHA programs, policies, or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to *Title 29 of the Code of Federal Regulations*. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693–1999. See also OSHA's website at **www.osha.gov**.

OSHA
Occupational Safety and Health Administration
U.S. Department of Labor
2002

Fire Protection and Prevention

The Occupational Safety and Health Administration (OSHA) requires employers to implement fire protection and prevention programs in the workplace. The regulations that apply to fire protection and prevention can be found mainly in Subpart F of the construction standards, though the requirement for a fire prevention program is first set out in Subpart C. The following sections of the construction standards contain requirements for fire protection that are of significance to roofing contractors:

1926.24 Subpart C, Fire protection and prevention programs
1926.150 Fire protection
1926.151 Fire prevention
1926.152 Flammable and combustible liquids
1926.153 Liquefied petroleum gas (LP-Gas)
1926.154 Temporary heating devices
1926.155 Definitions
1926.550 Subpart N, Cranes and derricks

Following this chapter, there is a list of fire safety work practices addressing many fire hazards found in the roofing workplace, including field operations and shop activities. Contractors should review the elements of the list most applicable to their companies' operations and consider including them in their companies' health and safety program.

Fire Protection

Fire is a chemical reaction that requires three elements to be present for the reaction to take place and continue. The three elements are:

- *Heat, or an ignition source*
- *Fuel*
- *Oxygen*

These three elements typically are referred to as the "fire triangle." Fire is the result of the reaction between the fuel and oxygen in the air. Scientists developed the concept of a fire triangle to aid in understanding of the cause of fires and how they can be prevented and extinguished. Heat, fuel and oxygen must combine in a precise way for a fire to start and continue to burn. If one element of the fire triangle is not present or removed, fire will not start or, if already burning, will extinguish.

Ignition sources can include any material, equipment or operation that emits a spark or flame—including obvious items, such as torches, as well as less obvious items, such as static electricity and grinding operations. Equipment

or components that radiate heat, such as kettles, catalytic converters and mufflers, also can be ignition sources.

Fuel sources include combustible materials, such as wood, paper, trash and clothing; flammable liquids, such as gasoline or solvents; and flammable gases, such as propane or natural gas.

Oxygen in the fire triangle comes from the air in the atmosphere. Air contains approximately 79 percent nitrogen and 21 percent oxygen. OSHA describes a hazardous atmosphere as one which is oxygen-deficient because it has less than 19.5 percent oxygen, or oxygen enriched because it has greater than 23.5 percent oxygen. Either instance is regarded by OSHA as an atmosphere immediately dangerous to life and health (IDLH) for reasons unrelated to the presence of fire. Depending on the type of fuel involved, fires can occur with much lower volume of oxygen present than needed to support human respiration.

Every roofing project has all three of the fire triangle elements present in abundance. The key to preventing fires is to keep heat and ignition sources away from materials, equipment and structures that could act as fuel to complete the fire triangle.

Fire Classifications

Fires are classified as A, B, C, D or K based on the type of substance that is the fuel for the fire, as follows:

Class A—fires involving ordinary combustibles, such as paper, trash, some plastics, wood and cloth. A rule of thumb is if it leaves an ash behind, it is a Class A fire.

Class B—fires involving flammable gases or liquids, such as propane, oil and gasoline

Class C—fires involving energized electrical components

Class D—fires involving metal. A rule of thumb is if the name of the metal ends with the letters "um," it is a Class D fire. Examples of this are aluminum, magnesium, beryllium and sodium. Class D fires rarely occur in the roofing industry.

Class K—fires involving vegetable or animal cooking oils or fats; common in commercial cooking operations using deep fat fryers

Fire Extinguishers

There are different types of fire extinguishers designed to put out the different classes of fire. Selecting the appropriate fire extinguisher is an

important consideration for a roofing contractor. The wrong extinguisher actually may make a fire emergency worse. For example, failing to use a C-rated extinguisher on energized electrical components may endanger workers by causing the extinguishing material to be electrified by the energized components that are on fire. C-rated fire extinguishers put out the fire by using a chemical that does not conduct electricity.

The following table illustrates the types of extinguishers, fire classes for which each is used and the limitations of each extinguisher.

Fire Extinguisher Type	*Class of Fire it Extinguishes*	*Extinguisher Limitations/ Comments*
Dry Chemical (multipurpose)	*A, B, C*	*Generally good for use in roofing industry*
Foam—alcohol-resistant and aqueous film-forming foam (AFFF) types	*B*	*Expensive; effective on Class B only; limited shelf life; generally not needed in roofing industry*
Water	*A*	*Good only for Class A fires*
Metal X	*D B, C;*	*Expensive; must be kept dry; ineffective on A, typically not needed in roofing industry*
Carbon Dioxide	*B, C*	*If used in confined areas, will create oxygen deficiency; not effective in windy conditions; can cause frostbite during discharge; typically not used in roofing industry*
Halon	*B, C*	*Expensive; not effective in windy conditions; toxic gases may be released in extremely hot fires because of decomposition; generally not used in roofing industry*
Potassium Acetate	*K*	*Expensive, wet chemical extinguisher for commercial cooking operations using oils and fats*

Roofing contractors typically purchase dry-chemical fire extinguishers because they can extinguish three fire classes (A, B and C).

OSHA requires a minimum-rated 10B fire extinguisher be provided within 50 feet of the point of job site use of more than 5 gallons of flammable or combustible liquids or 5 pounds of flammable gas. Examples of flammable and combustible liquids include gasoline, kerosene, acetone, MEK, single-ply adhesives, splice cleaners and asphalt cutback products. Fire extinguishers must be rated by a nationally recognized testing laboratory.

Extinguishers also must be inspected on a regular basis and maintained fully charged.

Using Fire Extinguishers

When using fire extinguishers, employees should employ the "PASS" system of early-stage firefighting.

P—Pull the pin on the extinguisher
A—Aim at the base of the fire
S—Squeeze the handle
S—-Sweep at the fire, moving from side to side

Employees should be instructed that if a fire cannot be extinguished using one full extinguisher, they should evacuate the site and let the fire department handle the situation.

Fire Prevention

Fire prevention requires segregating the three elements of the fire triangle. In practice, a method to achieve that goal is to post—and enforce—no-smoking signs around flammable liquids and gases and have fire watches on all work involving torch-applied materials of a minimum of two hours after the last torch is turned off.

Flammable and Combustible Liquids

Proper storage and handling of flammable and combustible liquids will help prevent fires from occurring; only approved, closed containers for storage of flammable or combustible liquids may be used under OSHA rules. Such containers include safety cans or containers approved by the U.S. Department of Transportation. A safety can is a container that has a self-closing lid, internal-pressure relief and flame arrestor with a capacity of not more than 5 gallons. Inexpensive, plastic cans without those features previously mentioned, such as those typically bought at hardware stores or gas stations, are not approved for use in roofing operations. However, manufacturers do sell plastic containers that meet the OSHA requirements for safety cans.

Flammable liquids that are extremely viscous, or difficult to pour, like single-ply adhesive, can be left in their original shipping containers. Similarly, OSHA allows the use of original containers of flammable liquids that are in quantities of one gallon or less.

Static electricity may be generated when transferring liquids, gases or solids through pipes or hoses. It is important to dissipate this electric charge when handling flammable and combustible materials. When transferring flammable or combustible liquids from one container to another, the two containers must be "bonded" together. The bonding process involves attaching a wire with alligator clips on each end to both containers. The clips must penetrate

the container coating and touch metal. You may need to score the paint with the alligator clips. To dissipate static, the container receiving the liquid must be in contact with the ground and not insulated from contact with the ground. For example, plastic or composite pickup truck bed liners prevent the flow of static electricity to ground because the liner does not conduct electricity. The receptacle container must have a clear path to ground, by direct contact or use of a grounding strap or wire, to effectively eliminate static.

Service or fueling areas at job sites must have a 20BC-rated fire extinguisher within 75 feet of each pump.

Safety cabinets allow for greater quantities of flammable and combustible liquids to be stored safely inside buildings. Up to 60 gallons of a flammable liquid or as much as 120 gallons of a combustible liquid may be stored indoors in a safety cabinet. Each cabinet must be labeled "Flammable—Keep Fire Away." Up to three cabinets may be stored in one room. Without a safety cabinet, only 25 gallons of either flammable or combustible liquids are allowed to be stored inside a building.

Liquefied Petroleum Gas

Liquefied petroleum gas (LP gas) is used widely in the roofing industry to heat kettles and torches. Because LP gas is a compressed gas, fairly large quantities can be stored in relatively small containers. As a point of reference, LP gas expands at a ratio of 270-to-1. This means that one liquid drop of LP gas would expand to a gas state 270 times greater in volume.

LP gas collects in low-lying areas because its vapor density is heavier than air. Employees should be warned that if they suspect a leak in a cylinder, they must not use fire to attempt to find the hole. Instead, they are to use soapy water and look for bubbles.

Employees should not attempt to extinguish fires involving LP gas. If an LP gas fire breaks out, employees should evacuate the area immediately and call the fire department. Fighting an LP gas fire requires specialized training that only the fire department can provide. Employee attempts to extinguish the fire could create larger hazards.

Torch-applied Roofing Materials

Torch-applied roofing materials pose a serious fire hazard to roofing contractors and building owners. Sometimes the hazards are obvious—such as torching to a combustible deck or near flammable liquids, while other concerns are less obvious—such as torching around drains or penetrations where flames can be drawn into a building.

Roofing contractors must instruct employees that they must:

- *Never torch directly to combustible decks or materials*
- *Never torch to areas that cannot be seen fully*
- *Not use torches near vents or air intakes*
- *Never use a torch to heat a propane tank that begins to frost on the outside*
- *Have appropriate fire extinguishers within easy reach at all times*

Whenever working with torch-applied roofing materials, fire-watch inspections must be conducted for at least two hours after the work has been completed and the last torch has been turned off.

More information on torch safety can be found in NRCA/MRCA Certified Roofing Torch Applicator Program at NRCA's Web site, www.nrca.net.

Fire Alarm Devices

OSHA requires an alarm system be established by an employer to alert workers on the job site and local fire departments of fire emergencies. Job-site telephones and employee entrances must have alarm codes and reporting instructions at employee entrances.

A roofing contractor's emergency action plan for the job site must include:

- *Emergency escape procedures*
- *Equipment operation procedures prior to evacuation*
- *Procedures to account for all employees*
- *Rescue and medical duties for those employees responsible for such duties*
- *Preferred means of reporting emergencies*
- *Names and titles of employees with duties under the plan*

Employee Training

OSHA requires that all employees be trained to use fire extinguishers. Training is required upon employment and at least annually thereafter. It is recommended the training session cover how to determine when a fire is too big to handle; what type of extinguisher to use; and the PASS system of early-stage firefighting. It also is recommended that live fire training be conducted periodically (this level of training is not needed each year). Live training exposes employees to the pressure released from a fire extinguisher when the handle is squeezed and provides hands-on practice extinguishing a fire. Some local fire departments and most fire extinguisher suppliers offer this type of
training.

All company fire-prevention training sessions should be documented. If an outside organization conducts the training, it would be a good idea to obtain training certificates for the attendees.

List of Safe Work Practices

Fire Protection and Prevention Safe Work Practices

[Company name] will take all necessary steps to prevent fires. Inspections during various operations will be made to ensure fire-prevention objectives are being met. The steps are listed below.

Reporting and Extinguishing a Fire

- *The fire department and area supervisor will be notified when a fire is spotted.*
- *All workers will be alerted and evacuated as needed.*
- *The PASS method will be used to extinguish the fire by those employees who have been properly trained.*
- *The area will be evacuated immediately if the fire is large.*

Fire Protection

- *Before each project begins, the project manager or designee will contact the local fire department and determine whether any variations from the company's standard fire-prevention procedures are required.*
- *No-smoking signs will be posted in all regulated areas.*
- *Only approved containers will be used to store flammable or combustible materials.*
- *All containers will be bonded together and grounded when transferring flammable or combustible liquids.*
- *All work areas will be kept free of debris and other combustible materials.*

- *Inside company-owned or leased buildings, fire extinguishers will be spaced no more than 100 feet apart and will have no less than a 2A rating for every 3,000 feet of protected building.*

- *All employees will be trained on the use of fire extinguishers initially upon hire and annually thereafter.*

- *No employee will be permitted to use an extinguisher without having been fully trained.*

- *Fire extinguishers will be stored at a distance no greater than 10 feet from torch users.*

- *A fire extinguisher, rated not less than 10B, will be provided within 50 feet of the location where more than 5 gallons of flammable or combustible liquids or 5 pounds of a flammable gas are used on a job site.*

- *Mops will be "spun out" and placed on a noncombustible surface at the end of each day on projects involving hot bitumen.*

- *A fire watch will be posted for two hours after work has concluded for torch-applied roof systems.*

Flammable and Combustible Liquid Storage

- *No more than 25 gallons of flammable and combustible liquids will be stored outside approved safety cabinets in indoor locations.*

- *No more than 60 gallons of flammable liquids will be stored inside an approved safety cabinet in indoor locations.*

- *Combustible liquids will not exceed 120-gallon capacity inside approved safety cabinets.*

- *The number of approved safety cabinets in one room will not exceed three.*

- *Gasoline will not be used as a solvent for cleaning.*

- *All containers will be labeled in accordance with OSHA's Hazard Communication Standard.*

- *Buildings or structures containing flammable liquids or gases must be constructed of fire-resistant material.*

- *Flammable liquids or gases will be kept away from heat and ignition sources including welding work or any other operation involving flames or sparks.*

Handling Flammable Gases

- *LPG cylinders will be placed on a firm foundation and secured in an upright position.*
- *All LPG cylinders will be equipped with valve-protection devices.*
- *LPG cylinders will not be stored closer than 10 feet to the kettle.*
- *LPG cylinders will be placed away from vehicular traffic.*
- *LPG cylinders will not be stored inside buildings.*
- *Acetylene bottles will be stored in the upright position and secured.*
- *When in transport or not in use, acetylene bottles will have caps in place.*
- *Oxygen cylinders must be stored at least 20 feet from acetylene cylinders.*

Handling Flammable and Combustible Liquids

- *During refueling operations, all engines and motors will be turned off and allowed to cool.*
- *Open flames or other ignition sources must be kept at least 50 feet away from flammable or combustible liquids.*
- *No smoking will be permitted during the fueling process.*
- *Containers being filled will be placed directly on the ground or a grounding strap attached to form a connection to ground.*
- *No flammable liquid or gas will be used unless it has been positively identified beforehand.*
- *Health and physical hazards will be communicated to employees in accordance with OSHA's Hazard Communication Standard before the product is used.*
- *When flammable liquids and gases are being transported, all Department of Transportation rules will be followed.*

Fire Extinguishers

- *In buildings, all fire extinguishers will be mounted on a wall and properly marked.*

- *All vehicles will carry at least one ABC-rated extinguisher.*

- *When at a job site, all employees will know the location of each fire extinguisher.*

- *Before using an extinguisher, all employees will be trained and familiar with the PASS method of firefighting.*

- *Each fire extinguisher will be inspected monthly to make sure it is in its designated location and has not been tampered with or actuated.*

- *Each fire extinguisher will be clearly visible with nothing obstructing or obscuring it from view.*

All fire extinguishers will be examined at least yearly and/or recharged or repaired to ensure operability and safety. A tag must be attached to show the maintenance or recharge date and the signature or initials of the person performing the service.

Preventing Violence at the Workplace

What Is Workplace Violence?

Workplace violence includes:

- physical assault
- threatening behavior
- verbal abuse
- harassment

Cal/OSHA's Three Types of Workplace Violence

- Type 1: A robbery or other criminal act committed by a stranger.
- Type 2: An assault by a client, customer, member, passenger, inmate, student, or other person who receives services from the victim.
- Type 3: A threat or violent act on the job by an employee, supervisor, former employee, or manager.

Five Warning Signs of Escalating Behavior

Warning Signs	Possible Responses
Confusion	
Behavior characterized by bewilderment or distraction. Unsure or uncertain of the next course of action.	• Listen to their concerns. • Ask clarifying questions. • Give them factual information.
Frustration	
Behavior characterized by reaction or resistance to information. Impatience. Feeling a sense of defeat in the attempt of accomplishment. May try to bait you.	• See steps above. • Relocate to quiet location or setting. • Reassure them. • Make a sincere attempt to clarify concerns.
Blame	
Placing responsibility for problems on everyone else. Accusing or holding you responsible. Finding fault or error with the action of others. They may place blame directly on you. Crossing over to potentially hazardous behavior.	• See steps above. • Disengage and bring second party into the discussion. • Use teamwork approach. • Draw client back to facts. • Use probing questions. • Create "Yes" momentum.
Anger - Judgment call required	
Characterized by a visible change in body posture and disposition. Actions include pounding fists, pointing fingers, shouting or screaming. This signals very risky behavior.	• Utilize venting techniques. • Don't offer solutions. • Don't argue with comments made. • Prepare to evacuate or isolate. • Contact supervisor and/or security office.
Hostility - Judgment call required	
Physical actions or threats which appear imminent. Acts of physical harm or property damage. Out-of-control behavior signals they have crossed over the line.	• Disengage and evacuate. • Attempt to isolate person if it can be done safely. • Alert supervisor and contact security office immediately.

Source: http://www.oshatrain.org/courses/mods/720signs.html (OSHAcademy - Occupational Safety & Health Training)

Emergency Preparedness and Response for Earthquakes

What is an earthquake?

An earthquake is a sudden, rapid shaking of the ground caused by the breaking and shifting of rock beneath the Earth's surface. This shaking can cause buildings and bridges to collapse; disrupt gas, electric, and phone service; and sometimes trigger landslides, avalanches, flash floods, fires, and huge, destructive ocean waves (tsunamis). Buildings with foundations resting on unconsolidated landfill, old waterways, or other unstable soil are most at risk. Buildings or trailers and manufactured homes not tied to a reinforced foundation anchored to the ground are also at risk since they can be shaken off their mountings during an earthquake. Earthquakes can occur at any time of the year.

What hazards are associated with earthquakes?

When an earthquake occurs in a populated area, it may cause deaths and injuries and extensive property damage. Ground movement during an earthquake is seldom the direct cause of death or injury. Most earthquake-related injuries result from collapsing walls, flying glass, and falling objects as a result of the ground shaking, or people trying to move more than a few feet during the shaking. Much of the damage in earthquakes is predictable and preventable.

What are aftershocks?

Aftershocks are smaller earthquakes that follow the main shock and can cause further damage to weakened buildings. After-shocks can occur in the first hours, days, weeks, or even months after the quake. Be aware that some earthquakes are actually foreshocks, and a larger earthquake might occur.

What can I do to prepare before an earthquake occurs?

Pick "safe places". A safe place could be under a sturdy table or desk or against an interior wall away from windows and bookcases, or tall furniture that could fall on you. The shorter the distance to move to safety, the less likely you will be injured. Injury statistics show that people moving as little as 10 feet during an earthquake's shaking are most likely to be injured.

Practice drop, cover, and hold-on in each safe place. Drop under a sturdy desk or table and hold on to one leg of the table or desk. Protect your eyes by keeping your head down. Practice these actions so that they become an automatic response.

Practice drop, cover, and hold-on at least twice a year. Frequent practice will help reinforce safe behavior. When an earthquake or other disaster occurs, many people hesitate, trying to remember what they are supposed to do. Responding quickly and automatically may help protect you from injury.

Wait in your safe place until the shaking stops, then check to see if you are hurt. You will be better able to help others if you take care of yourself first, then check the people around you. Move carefully and watch out for things that have fallen or broken, creating hazards. Be ready for aftershocks.

Be on the lookout for fires. Fire is the most common earthquake-related hazard, due to broken gas lines, damaged electrical lines or appliances, and previously contained fires or sparks being released.

If you must leave a building after the shaking stops, use the stairs, not the elevator. Earthquakes can cause fire alarms and fire sprinklers to go off. You will not be certain whether there is a real threat of fire. As a precaution, use the stairs.

If you're outside in an earthquake, stay outside. Move away from buildings, trees, streetlights, and power lines. Crouch down and cover your head. Many injuries occur within 10 feet of the entrance to buildings. Bricks, roofing, and other materials can fall from buildings, injuring persons nearby. Trees, streetlights, and power lines may also fall, causing damage or injury.

Inform workers of the plan. Everyone in your workplace should know what to do if an earthquake occurs.

Get training. Take a first aid class from your local Red Cross chapter. Get training on how to use a fire extinguisher. Keep your training current. Training will help you to keep calm and know what to do when an earthquake occurs.

Discuss earthquakes with workers. Everyone should know what to do. Discussing earthquakes ahead of time helps reduce fear and anxiety and lets everyone know how to respond.

In *most* situations, you will reduce your chance of injury from falling objects (and even building collapse) if you immediately:

- **DROP down onto your hands and knees** before the earthquake would knock you down. This position protects you from falling but still allows you to move if necessary.
- **COVER** your head and neck (and your entire body if possible) under the shelter of a sturdy table or desk. If there is no shelter nearby, get down near an interior wall or next to low-lying furniture that won't fall on you, and cover your head and neck with your arms and hands. Try to stay clear of windows or glass that could shatter or objects that could fall on you.
- **HOLD ON to your shelter** (or to your head and neck) until the shaking stops. Be prepared to move with your shelter if the shaking shifts it around.

Check for Injuries:

☐ Check your first aid kit or the front pages of your telephone book for detailed instructions on first aid measures.
☐ If a person is bleeding, put direct pressure on the wound. Use clean gauze or cloth, if available.
☐ If a person is not breathing, administer rescue breathing.
☐ If a person's heart has stopped, begin CPR (cardiopulmonary resuscitation).
☐ If a person's clothes catch fire, have them stop, drop, and roll.
☐ do not move seriously injured persons unless they are in immediate danger of further injury.
☐ Cover injured persons with blankets or additional clothing to keep them warm.
☐ Get medical help for serious injuries.
☐ carefully check children or others needing special assistance.

Office First Aid Kit is located: _____

Flashlights are located (highly recommended): _____

Examine the area for fire hazards and call 911 if there is a fire hazard.

Outside meeting place is: _____

Approved by: _____ MD _____

Dated: _____

Source:
www.espfocus.org Emergency Survival Program) 07/06
Centers for Disease Control and Prevention **cdcinfo@cdc.gov**
Downloded 11/12

SECTION	Approval date:	
Access/Safety	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Fire Safety and Prevention and Emergency Non-Medical Procedures	**Revision date:**	

POLICY:

Site shall be maintained in a manner that provides a safe environment for all patients, visitors, and personnel. Site shall meet all city, county and state fire safety and prevention ordinances. Site staff shall receive training and information on fire safety & prevention and emergency non-medical procedures.

PROCEDURE:

I. **SAFE ENVIRONMENT**

The provider/designee will ensure the following fire and safety precautions:

- Lighting is adequate in all areas
- Exit doors and aisles are unobstructed and egress (escape) accessible.
- Exit doors are clearly marked with “Exit” signs.
- Clearly diagrammed “Evacuation Routes” for emergencies are posted in visible locations.
- Electrical cords and outlets are in good working condition
- At least one type of firefighting/protection equipment is accessible at all times

Staff will be responsible to correct any “unsafe” situation, and/or report the situation to the provider/designee who will make/arrange for correction.

II. **INFORMATION AND TRAINING**

Fire Safety & Prevention and Non-Medical Emergency information shall be available on site. Staff shall be informed of the location of the information and how to use the information. Staff training on fire safety & prevention and emergency non-medical procedures are verifiable and may be part of staff education documented in:

- Informal or formal in-services
- New staff orientation
- External training courses

Fire Safety & Prevention and Non-Medical Emergency procedure training topics shall include:

- Evacuation routes and exits for the exam rooms, office suites, and building
- Evacuation procedures
- Location of fire alarms, extinguishers, sprinklers, and smoke detectors
- Emergency phone numbers
- Workplace violence procedures *including emergency numbers*

Medical Emergency Equipment Policy and Procedures

Purpose:
To provide appropriate evaluation and management of patients in emergency situations so as to optimize the patient's health and well being and to have equipment available to meet the needs of the patients in the event of a medical emergency.

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:

1) establish and maintain a patent/open airway, and
2) manage anaphylactic reaction.

Emergency medical equipment: Emergency equipment and medication, appropriate to patient population, are available in an accessible location. 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. Documented evidence that emergency equipment is checked at least monthly may include a log, checklist or other appropriate method(s).

Emergency phone number list: Posted list 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). List should be dated, and updated annually.

Airway management: Without the ability to adequately maintain the patient's airway, all other interventions are futile. Minimum airway control equipment includes a wall oxygen delivery system or portable oxygen tank, oropharyngeal airways, nasal cannula or mask, and Ambu Bag. Various sizes of airway devices appropriate to patient population within the practice are on site. 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 need not be connected to oxygen tank, but must be kept in close proximity to tank. Health care personnel at the site must demonstrate that they can turn on the oxygen tank.

Anaphylactic reaction management: Severe allergic reaction can cause urticaria (hives), hypotension, bronchospasm, wheezing and pulmonary edema. Minimum equipment includes Epinephrine 1:1000 (injectable), Benadryl 25 mg. (oral), or Benadryl 50 mg/ml (injectable), tuberculin syringes, alcohol wipes. 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).

Site Specific Emergency procedures: Staff is able to describe site-specific actions or procedures for handling medical emergencies until the individual is stable or under care of local emergency medical services (EMS). It is ***not sufficient*** for provider/staff to state "we call 911". If a site does not have basic medical equipment and medication for handling airway and anaphylactic medical emergencies, there is a written procedure for providing immediate emergent medical care on site until the local EMS is on the scene and has taken over care/treatment. 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.

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, and 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.

Section 51056 of Title 22 of the *California Code of Regulations*.
California Department of Health Services Medi-Cal Managed Care Division
Downloaded 11/12

Evacuation Plans and Procedures eTool

Employee Alarm Systems » Alarm Systems Checklist

GENERAL REQUIREMENTS	YES	NO
1. Does your plan include a way to alert employees, including disabled workers, to evacuate or take other action, and how to report emergencies?	○	○
2. Have you established an employee alarm system that complies with [29 CFR 1910.165]? [29 CFR 1910.38(d)]	○	○
3. If the employee alarm system is used for alerting fire brigade members, or for other purposes, is a distinctive signal used for each purpose? [29 CFR 1910.38(d)]	○	○
4. Does the employee alarm system provide warning for necessary emergency action as called for in the emergency action plan, or for reaction time for safe escape of employees from the workplace or the immediate work area, or both? [29 CFR 1910.165(b)(1)]	○	○
5. Can alarms be heard, seen, or otherwise perceived by everyone in the workplace? [29 CFR 1910.165(b)(2)]	○	○
6. Do you provide an auxiliary power supply if electricity is shut off? [29 CFR 1910.165(b)(2)]	○	○
7. Do you ensure that alarms are distinctive and recognized by all employees as a signal to evacuate the work area or perform actions identified in your plan? [29 CFR 1910.165(b)(3)]	○	○
8. Have you made available an emergency communications system such as a public address system, portable radio unit, or other means to notify employees of the emergency and to contact local law enforcement, the fire department, and others? [29 CFR 1910.165(b)(4)]	○	○
9. Have you established procedures for sounding emergency alarms in the workplace? [29 CFR 1910.165(b)(5)]	○	○

INSTALLATION AND RESTORATION	YES	NO

INSTALLATION AND RESTORATION	YES	NO
1. Are only approved devices, components, combinations of devices, or systems used? Steam whistles, air horns, strobe lights or similar lighting devices, or tactile devices meeting the requirements of this section are considered to meet this requirement for approval. [29 CFR 1910.165(c)(1)]	○	○
2. Are all employee alarm systems restored to normal operating condition as soon as possible after each test or alarm? Spare alarm devices and components must be readily available. [29 CFR 1910.165(c)(2)]	○	○

MAINTENANCE AND TESTING	YES	NO
1. Are all employee alarm systems in proper working condition, except when undergoing repairs or maintenance? [29 CFR 1910.165(d)(1)]	○	○
2. Is the reliability and adequacy of non-supervised employee alarm systems tested every two months? Use a different actuation device in each test of a multi-actuation device system. [29 CFR 1910.165(d)(2)]	○	○
3. Are power supplies maintained or replaced as often as is necessary to assure a fully operational condition? Provide back-up alarms when systems are out of service. [29 CFR 1910.165(d)(3)]	○	○
4. Is employee alarm circuitry installed after January 1, 1981 supervised and does it provide positive notification to assigned personnel whenever a deficiency exists in the system? [29 CFR 1910.165(d)(4)]	○	○
5. Are the servicing, maintenance and testing of employee alarms done by properly trained persons? [29 CFR 1910.165(d)(5)]	○	○

MANUAL OPERATION	YES	NO
1. Are manually activated alarms unobstructed, conspicuous and readily accessible? [29 CFR 1910.165(e)]	○	○

UNITED STATES
DEPARTMENT OF LABOR

Occupational Safety & Health Administration
200 Constitution Ave NW
Washington, DC 20210
800-321-6742 (OSHA)

EMERGENCY PROTOCOL & CONTACT LIST

TYPES / SERVICE	CONTACT INFORMATION
ALL EMERGENCIES:	**911**
POISON CONTROL:	**(800) 411-8080**
CHILD ABUSE HOTLINE:	_____
ELDER ABUSE HOTLINE:	**(877) 477-3646**
DOMESTIC VIOLENCE HOTLINE:	**(800) 799-7233**
LOCAL POLICE DEPARTMENT:	_____
LOCAL FIRE DEPARTMENT:	_____
MANAGER/SUPERVISOR NUMBER:	_____

Type of emergency employee alert system used on site: _____

Back-up system: _____

(If 10 or less employees, direct verbal communication is acceptable and does not require a back-up system)

The MEDICAL EMERGENCY KIT is located at _____

The INVENTORY LIST of emergency drugs and their DOSAGE CHARTS are stored with the MEDICAL EMERGENCY KIT.

The OXYGEN TANK is located at _____ and is FULL; secured; has a flow meter and a regulator; and has a mask/cannula attached.

In the event of a MEDICAL EMERGENCY, the following personnel are responsible for:

_____ shall call 911

_____ shall start CPR

_____ shall retrieve the MEDICAL EMERGENCY KIT

_____ shall retrieve the OXYGEN TANK

_____ shall remain with family and/or other patients

Approved by: _____ Date: _____

Dates of Annual Review (for updates): _____ _____ _____

_____ _____ _____

_____ _____ _____

OFFICE EMERGENCY PROTOCOL

IN CASE OF EMERGENCY:

FRONT OFFICE RECEPTIONIST

In charge of communication:

a. **Make phone call to paramedics**
b. **Make phone call to ambulance**
c. **Make phone call to poison control (if applicable)**
d. **Make phone call to Emergency Room (If applicable)**
e. **Make phone call to a Specialist (if applicable)**

BACK OFFICE MANAGER

In charge of coordination:

a. **Get oxygen, blanket, and IV supplies**
b. **Get crash cart**
c. **Emergency mediation standby (e.g. Epinephrine)**
d. **Communicate with patients family if necessary**
e. **Monitor vital signs and stay with patient**

BACK OFFICE ASSISTANT

In charge of assisting physician:

a. **Perform EKG**
b. **Assist in CPR**
c. **Assist with other procedures as necessary**

Crash Cart, IV Supplies, Oxygen, ETC, are stored together in an easily accessible location.

INFORMATION FOR PRACTITIONER OFFICES

Poison Emergency in the U.S. call		(800) 222-1222
Child Abuse Hotline	Los Angeles County	(800) 540-4000 within CA
		(213) 639-4500 outside CA
		(800) 272-6699 TDD
	Riverside County	(800) 442-4918 or (877) 922-4453
	San Bernardino County	(800) 827-8724 or (909) 384-9233
Elder Abuse Hotline	Los Angeles County	(877) 477-3646 or (877) 4-R-Seniors
		(213) 351 -5401 outside California
	Riverside County	(800) 491-7123 or (951) 358-6998
	San Bernardino County	(877) 565-2020

Vaccine Information Sheets www.immunize.org

Interpreter Services

- SCAN Health Plan (800) 559-3500 Mon-Fri 7:00 am to 6:00 pm
- TDD (Telecommunication Device for the Deaf) (877) 486-2048
- Language Line Services (800) 752-6096 (fee for service)

DHCS Medical Emergency Response Guidelines for PCP Clinic

Emergency health care services are available and accessible 24 hours a day, 7 days a week (Facility Site Review, I. Access/Safety Guidelines, D.)

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
- ☐ When the MD or 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.
- ☐ Emergency equipment and medication, appropriate to patient population, are available in an accessible location and is ready for use.
- ☐ 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.

- ☐ Documented evidence that emergency medication and equipment is checked at least monthly may include a log, checklist or other appropriate method(s).

EMERGENCY MEDICAL EQUIPMENT:

Minimum emergency equipment is available on site to:

- ☐ Establish and maintain a patent/open airway.
- ☐ Manage emergency medical conditions.

EMERGENCY PHONE NUMBER LIST:

- ☐ Post emergency phone number list that is dated with telephone numbers updated annually and as changes occur List must include:
  - ☐ 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)

AIRWAY MANAGEMENT:

Clinic must have minimum airway control equipment, to include:

- ☐ Wall oxygen delivery system or portable oxygen tank (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 need not be connected to oxygen tank, but must be kept in close proximity to tank.
  - ☐ Health care personnel at the site must demonstrate that they can turn on the oxygen tank**.**
- ☐ Nasal cannula or mask, oropharyngeal airways,
- ☐ Bulb syringe
- ☐ Ambu Bag as appropriate to patient population. (Mask should be replaced when they can no longer make a solid seal)
- ☐ Various sizes of airway devices appropriate to patient population within the practice are on site.

EMERGENCY MEDICATION/ANAPHYLACTICE REACTION MANAGEMENT:

DHCS Medical Emergency Response Guidelines for PCP Clinic – 2019

COMMUNICATION		PHASE	EMERGENCY RESPONSE	
ACTION	**RESPONSIBILITY**		**ACTION**	**RESPONSIBILITY**
Call 911, activate Emergency Medical Services (EMS): Provide address, clinic name,phone# Describe situation Vital Signs Level of consciousness Degree of urgency	Clinic Staff with health information provided by Primary Care Provider	**TRIAGE**	Check ABCs • airway, breathing, circulation • vital signs • check blood sugar, if indicated • check for medic alert	Primary Care Provider
			Complete brief history and P.E.	Primary Care Provider
			Maintain a safe environment for staff and client	Clinic Staff
Establish Leadership and direct activities	Primary Care Provider	**MANAGEMENT**	Obtain required equipment as per emergency protocol	Clinic Staff
Obtain immediate assistance within the office	Primary Care Provider		Move client as required	Primary Care Provider
Use Emergency documentation to note treatments and progress	Primary Care Provider		Do secondary survey, detailed physical examination	Primary Care Provider
Obtain history from next of kin and update them on situation	Primary Care Provider		Assess need for immediate treatment	Primary Care Provider
Communicate with and relocate other clients as needed	Clinic Staff		Initiate treatment according to appropriate protocol with available equipment and medication	Primary Care Provider
Provide patient information and medication sheet for EMS	Clinic Staff			Primary Care Provider
Direct staff member to meet EMS team in parking lot, hold elevator, etc.	Clinic Staff	**TRANSFER**	Reevaluate status and response to therapy	Primary Care Provider
Most responsible primary care provider to sign patient over to EMS	Primary Care Provider		Transfer for definitive care to EMS	Primary Care Provider
Provide written copy of documentation & medication sheet to EMS	Clinic Staff			
MD, PA, NP, or RN to call hospital emergency dept. & update status. Note on documentation.	Primary Care Provider			
MD, PA, NP, or RN to update next of kin. Permission from pt., if possible	Primary Care Provider	**FOLLOW-UP**	Restock Emergency Cart & re-order medication as required	Clinic Staff
Identify opportunities for improvement and implement changes accordingly	Primary Care Team Manager in collaboration with Primary Care Team		Provide medical follow-up in acute case setting as required	Primary Care Provider
			If critical incident, complete appropriate paperwork and steps for reporting. Debrief staff	Team Manager

*** Please confirm all dosages with manufacturer of actual medications on site***

Emergency medications dosage chart – sample

<table>
<tr><th>Rx name</th><th>Adults</th><th>Pediatrics</th></tr>
<tr><td>Albuterol sulfate[1] inhalation solution (0.0836% - 2.5 mg/ 3 ml)</td><td>2.5mg to 5mg every 20 minutes for 3 doses, then 2.5 mg to 10 mg every 1 to 4 hours PRN.</td><td>Children: 2.5 mg to 5 mg every 20 minutes for 3 doses, then 2.5 mg to 10 mg every 1 to 4 hours PRN.
Infant: 2.5 mg every 20 minutes for the first hour PRN; if there is rapid response, can change to every 3 to 4 hours PRN.</td></tr>
<tr><td>Albuterol sulfate[1] inhalation aerosol metered dose (90 mcg/actuation)</td><td>4 to 8 inhalations every 20 minutes for up to 4 hours, then 1 to 4 hours PRN.</td><td>Children: 2 to 10 inhalations every 20 minutes for 2 to 3 doses; if rapid response, can change to every 3 to 4 hours PRN.
Infant: 2 to 6 inhalations every 20 minutes for 2 to 3 doses; if there is rapid response, can change to every 3 to 4 hours PRN.</td></tr>
<tr><td>Chewable aspirin 81 mg (not enteric coated)</td><td>For myocardial infarction (MI):
Chew 2 to 4 tablets upon presentation or within 48 hours of stroke.</td><td>For myocardial infarction (MI):
Chew 2 to 4 tablets upon presentation or within 48 hours of stroke.
*Aspirin is not recommended for patients less than 18 years of age who are recovering from chickenpox or flu symptoms due to association with Reye syndrome.</td></tr>
<tr><td>Benadryl[1] HCL injection, USP (50 mg/ml)</td><td>10 mg to 50 mg IV/IM (not to exceed 400 mg/day)
If IV route, IV push at a rate of ≤25 mg/min.</td><td>Children: 1 to 2 mg/kg/dose IV/IM (not to exceed 50 mg/dose).
If IV route, IV push at a rate of ≤25 mg/min.
Infant: 1 to 2 mg/kg/dose IV/IM (not to exceed 50 mg/dose).</td></tr>
<tr><td>Benadryl[2] liquid 12.5 mg/5 ml</td><td>25 to 50 mg every 4 to 6 hours; max 300 mg/day.</td><td>Child weight (pound):
<table>
<tr><th>lbs</th><th>20 to 24</th><th>25 to 37</th><th>38 to 49</th><th>50 to 99</th></tr>
<tr><td>ml</td><td>4</td><td>5</td><td>7.5</td><td>10</td></tr>
</table></td></tr>
<tr><td>Benadryl[1] chewable 12.5 mg</td><td>2 to 4 chewable tablets every 4 to 6 hours.</td><td>Child weight (pound):
<table>
<tr><th>lbs</th><th>20 to 24</th><th>25 to 37</th><th>38 to 49</th><th>50 to 99</th></tr>
<tr><td>tablet</td><td>N/A</td><td>1</td><td>1 ½</td><td>2</td></tr>
</table></td></tr>
<tr><td>Benadryl[1] tablet 25 mg (Oral)</td><td>Take 25 mg to 50mg by mouth.</td><td>Not preferred. Refer to parenteral route or oral solution.</td></tr>
<tr><td>Epinephrine[1] injection, 1:1,000
(1 mg/ml)</td><td>0.3 to 0.5 mg IM may repeat every 5 to 10 minutes.</td><td>0.01 mg/kg IM (up to maximum of 0.3 mg). May repeat every 5 to 10 minutes as needed.</td></tr>
</table>

Rx name	Adults	Pediatrics
Epinephrine[2] injection, 1:10,000 (0.1 mg/ml)	0.1 to 0.25 mg IV (1 to 2.5 ml of 1:10,000 solution) injected slowly once.	**Infant:** 0.05 mg IV slowly once, may repeat at 20 to 30 minute intervals as needed. **Neonates:** 0.01 mg/kg of body weight IV slowly once.
Epinephrine[1] Injection, USP auto-injector: **Epipen Jr** (Epinephrine 0.15 mg) **Epipen** (Epinephrine 0.3 mg) **Auvi Q** (Epinephrine 0.1 mg, 0.15 mg, 0.3 mg)	**> 66 lbs**: 0.3 mg/dose IM or subcutaneous into the anterolateral aspect of the thigh. **> 66 lbs**: 0.3mg IM or subcutaneous into anterolateral aspect of the thigh, through clothing if necessary.	**33 to 66 lbs**: 0.15 mg/dose IM or subcutaneous into the anterolateral aspect of the thigh. **< 33 lbs:** Not recommended. **33 to 66 lbs**: 0.15mg IM or subcutaneous into anterolateral aspect of the thigh, through clothing if necessary. **16.5 - 33 lbs**: 0.1mg IM or subcutaneous into anterolateral aspect of the thigh, through clothing if necessary.
Naloxone (Narcan)[1] injection solution injection (0.4, or 1 mg/mL): **Naloxone** auto injector (Evzio) (2 mg in 0.4 ml) **Naloxone** nasal spray (4 mg/actuation)	0.4 mg to 2 mg IV, IM, or subcutaneous up to a total dose of 10 mg, may repeat every 2 to 3 minutes as needed. 2 mg IM or subcutaneous into the anterolateral aspect of the thigh, may repeat same dose after 2 to 3 minutes. Spray 4 mg into 1 nostril. If desired response is not achieved after 2 to 3 minutes, give a second dose intranasally into alternate nostril.	0.01 mg/kg IV, IM or subcutaneous, may repeat dose every 2 to 3 minutes as needed. 2 mg IM or subcutaneous into the anterolateral aspect of the thigh, may repeat same dose after 2 to 3 minutes. (Under 1 year old, thigh muscle should be pinched while administering injection). Spray 4 mg into 1 nostril. If desired response is not achieved after 2 to 3 minutes, give a second dose intranasally into alternate nostril.
Nitrostat (Nitroglycerin) SL tablets (0.3 mg or 0.4 mg) **Nitroglycerin spray** (0.4 mg)	0.3 mg to 0.4 mg sublingually or in buccal pouch at onset, may repeat in 5 minutes; max 3 tabs in 15 minutes. Prophylaxis: 5 to 10 minutes before activity. Spray 0.4 mg (1 spray) sublingually every 5 minutes up to 3 doses.	Not recommended.
Glucagon for injection (emergency medication for low blood sugar) 1 mg (1 unit)	**< 20kg**: 0.5 mg or 20 to 30 mcg/kg IM, IV or subcutaneous. **> 20 kg**: 1 mg IM, IV or subcutaneous.	**< 20 kg**: 0.5 mg or 20 to 30 mcg/kg IM, IV or subcutaneous **> 20 kg**: 1 mg IM, IV or subcutaneous (If the patient does not respond in 15 minutes, may give 1 to 2 more doses).

Rx name	Adults	Pediatrics
Glucose tablet	If the patient does not respond in 15 minutes, may give 1 to 2 more doses. 15 gm (3 to 4 tablets) by mouth, may repeat in 15 minutes if hypoglycemic symptoms do not resolve.	**Children:** 10 gm to 20 gm (0.3gm/kg) by mouth, may repeat in 15 minutes if hypoglycemic symptoms do not resolve. **Infant:** Not preferred. Parenteral route recommended (IV dextrose or IM glucagon).
Ammonia[2] inhalants	Crack open one (1) capsule.	Same as adult.
Lidocaine[2] 1% HCL Inj. USP 10 mg/ml (50 ml MDK)	Use only the 10% solution for IM injection. 300 mg in deltoid or thigh muscle.	Individualize.
Sodium chloride[2] **0.9%** Injection USP (1000 mL)	125 drops / minute	**Depends on age:** **1 to 4 years old:** 40 drops/minute **5 to 10 years old**: 60 drops/minute
Solu-Medrol[2] 125 mg/ml injection, USP 2 ml single dose vial	**Initial dosage**: 10 to 40 mg IV, IM	**Initial dosage**: 0.11 to 1.6 mg/kg/day in 3 to 4 divided doses IV,IM
Oxygen delivery system – tank at least three-quarters full	Can consider any oxygen delivery systems if appropriate.	**Children:** Nasal prongs or nasal catheters preferred; can consider face mask, bead box, or incubator for older children. **Infant:** Nasal prongs or nasal catheters preferred.
Oxygen delivered 6 to 8 L/minute	6 to 8 L/minute	**Children:** 1 to 4 L/minute **Infant:** 1 to 2 L/minute

[1] Only one emergency medication strength or route required.

[2] Not required; optional emergency medications only.

The material in this document is a knowledge-sharing tool provided by the FSR team to enhance compliance with Facility Site Review requirements. All content is for informational purposes and may be used and/or modified according to site-specific practices. Ensure appropriate review and approval by site management prior to adoption.

Management of Anaphylaxis

(EXTREMELY RARE REACTION TO IMMUNIZATIONS)

Anaphylaxis, a potentially life-threatening acute systemic allergic reaction to a foreign substance, is extremely uncommon after immunization. Nonetheless, immunization clinic staff should have basic knowledge on how to recognize and initiate "first-aid" treatment of this reaction.

Anaphylaxis must be distinguished from simple fainting (vasovagal syncope) which can occur before, during or shortly after injection. Persons experiencing this reaction may become pale and feel faint, or they may suddenly collapse unconscious but with a steady pulse and normal respiration.

- Persons feeling faint should lie flat or sit in the head-down position for several minutes.
- Person who faint completely should be placed flat with the feet (not the head) somewhat elevated. After they regain consciousness, they should be allowed to rest in a quiet area for 10 minutes.

Anaphylaxis usually begins at least several minutes after injection of an offending substance. Initial symptoms typically include several of the follow: sneezing, coughing, itching, "pins and needles" sensation of the skin, flushing, facial edema, urticaria ("hives"), and anxiety. In severe cases, these symptoms may be followed by progressive dypsnea (with or without audible wheezing or stridor due to lower and/or upper airway narrowing) and/or hypotension which may progress to shock and collapse, with a weak and fast or irregular pulse.

The following is a guideline for IMMEDIATE "first aid" medical treatment of anaphylaxis that should be given in immunization clinics where more sophisticated medical attention and equipment (oxygen, intravenous medication, etc….) are not immediately available.

Nurses can legally initiate these emergency treatment measures (Business and Professions Code 2725d):

1. Call emergency medical / paramedic staff.

2. Apply tourniquet lightly (not so tight as to stop arterial pulse) above injection site, unless this is impossible (as in deltoid or gluteal area injection).

3. Inject intramuscularly into the deltoid (not in the same are as the vaccine injection) **aqueous 1:1000 epinephrine (adrenaline)** according to the following approximate dosage:

< 12 months	0.05 ml
1-4 years old	0.15 ml
5-9 years old	0.3 ml
>10 years old	0.5 ml

   If no improvement occurs within 3-4 minutes, repeat this intramuscular dose. Monitor respiration, pulse, and (if a sphygmomanometer is available) blood pressure. The same epinephrine dose can be repeated every 10-15 minutes, if needed.

4. As an adjunct to epinephrine (but not a replacement), **Benadryl (diphenhydramine hydrochloride), 50 mg/ml,** can be given once intramuscularly (at a different site than the epinephrine) in the following approximate dosage:

Under age 2 years	0.25 ml
Ages 2-4 years	0.5 ml
Ages 5-11 years	1.0 ml
>Age 12 years and Adults	2.0 ml

SECTION	Approval date:	
Access/Safety	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Emergency Medical Procedures	**Revision date:**	

POLICY:

Emergency health care services shall be available and accessible twenty-four hours a day, seven days a week.

PROCEDURE:

I. **EMERGENCY MEDICAL EQUIPMENT**

Minimum emergency medical supplies/equipment, sufficient to establish and maintain a patent/open airway and manage anaphylactic reactions, shall be maintained in the facility. The equipment will include:

A. A wall oxygen delivery system or secured portable oxygen tank maintained at least ¾ full. An oxygen delivery system which includes population-appropriate size (pediatric and adult): ambu-bag with face mask that creates proper seal, nasal cannula or oxygen mask, tubing, and bulb syringe.
   - Providers may NOT use small oxygen tanks where the liter flow cannot be adjusted. There is no size requirement for the tank, however, it must reflect the content balance in increments of ¼, ½, ¾, and full. The oxygen should last long enough to handle an emergency until the arrival of the emergency medical response team.
   - Office staff will know how to turn on and regulate the oxygen flow.

B. Benadryl 25 mg (oral) or Benadryl 50 mg/ml (injectable), Epinephrine 1:1000 (injectable), Naloxone, chewable aspirin 81 mg (at least 4 tablets), nitroglycerine spray/tablet, bronchodilator medication (solution for nebulizer or metered dose inhaler), glucose, appropriate sizes of ESIP syringes and alcohol wipes.

C. Emergency medication dosage chart (see attached).

The supplies/equipment will be located “together” in an accessible location allowing for retrieval by all staff members without the use of assistive devices.

The supplies and equipment shall be checked for expiration and operating status at least monthly. Staff responsible for checking the equipment/supplies shall document:
   - The date the supplies/equipment were checked, and
   - His/her initials verifying that equipment is in working order, the oxygen tank is at least ¾ full, the supplies are within expiration date and the medication dosage chart is present.

Replacing/restocking supplies:

- An extra oxygen tank will be maintained onsite -OR- each time the oxygen tank is used, the remaining supply will be checked. If the tank is ¾ or less full, the supplier will be called to replace the used tank with a full tank.
- The month prior to the noted expiration date, the supplies/medication will be ordered to ensure delivery before the supplies actually expire.
- The medication and supplies will be ordered and or replaced immediately after use.

II. EMERGENCY SERVICES TRAINING

All staff members will be trained on the emergency medical protocol. Staff will be able to:

- Describe facility-specific actions, and
- Locate written emergency procedures and information.

Training shall be completed upon hire and when updates to policy are made.
Training shall be documented.

III. EMERGENCY INFORMATION

Emergency phone numbers will be posted in an accessible and prominent location (e.g., front and back office). Posted list includes local emergency response services (e.g., fire, police/sheriff, ambulance), emergency contacts (e.g., responsible managers, supervisors), and appropriate State, County, City, and local agencies (e.g., local poison control number).

Emergency phone number list shall be dated, and telephone numbers updated annually and as changes occur.

IV. EMPLOYEE ALARM/ALERT SYSTEM

In the event of a fire or other emergency, employees are notified as soon as possible using the employee alarm/alert system (e.g., manual pull box alarms, public address systems, radio, telephones). Back-up means of alarm/alert (e.g., employee runners, air horns) shall be provided when systems are out of service. For those with 10 or fewer employees, direct voice communication is acceptable (provided all employees can hear the alarm or alert) and do not need a back-up system.

Type of Emergency Employee Alarm/Alert System used on site: _____
Back-up system: _____

SECTION	Approval date:	
Clinical Services	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Medical and Lab Equipment Maintenance	**Revision date:**	

POLICY:

Medical and Laboratory equipment used for patient care shall be properly maintained.

PROCEDURE:

II. MAINTENANCE OF MEDICAL EQUIPMENT

A. Operating manuals for medical and lab equipment shall be maintained on site.

B. Operating manuals will be the reference for planning routine maintenance schedules for equipment.

C. If operating manuals are not available, an annual cycle for safety/calibration service shall be adopted.

D. Documented proof of servicing shall be maintained on site and may be in the following form:

1. A receipt listing all equipment serviced and date of service
2. Stickers applied to equipment noting the date of service
3. Work orders/receipts for repair of equipment
4. A handwritten log with dates and results of calibration (such as for a Hemocue)

II**.** MALFUNCTIONING EQUIPMENT

A. Staff shall inform provider/designee of any equipment found to be malfunctioning or out of service.

1. Provider/designee will arrange for repair or replacement of malfunctioning equipment.
2. Documented proof of repair will be maintained on site.

III**.** QUALIFIED PERSONNEL

A. Qualified staff assigned to operate equipment shall be trained on appropriate use and maintenance

* This is a resource list only. You are not required by SCAN to utilize these vendors

FACILITY RESOURCE LIST		
CALIBRATION COMPANIES		
INSTRUMENT REPAIR NETWORK 6920 Knott Ave Ste E Buena Park CA 90621 (562)229-9778	SODEXHO HEALTH CARE SERVICES 3002 Dow Avenue # 110 Tustin, Ca 92780 (800) 559-4467	
QUEST DIAGNOSTICS, INC 8401 Fallbrook Avenue, West Hills, CA 91304 (800) 877-2515	STEVE MCMANUS MEDICAL SURGICAL, INC. 5061 Duncan Westminster, CA 92683 (877) 395-9567	REDMED 9330 Jersey Blvd. Rancho Cucamonga, CA 91730 (800) 733-6334
MEDICAL EQUPIMENT CALIBRATION (310) 666-4922	MEDI CALL MEDICAL EQUIPMENT REPAIR 1470 Pomona Road, #F Corona, CA 92882 (951) 279-7731	DAYLIGHT MEDICAL (800) 956-5576
BIOHAZARD WASTE HANDLERS		
TCI BURNING SERVICE OF SO. CALIF. 241 W. laurel Street Colton, CA 92324	ENSERV WEST, LLC 2462 Santa Fe Avenue Vista, CA 92084 (760) 727-6120	STERICYCLE Multiple Dispatch Centers throughout California (866) 783-7422
MEDWASTE MANAGEMENT 11420 Alameda St. Ste 3 90262 Lynwood, CA 90262 (866)254-5105	MEDI-WASTE DISPOSAL 235 Deininger Circle Corona, CA 92880 (855) 449-6334	
MEDICAL SUPPLY COMPANIES		
MTS HEALTH SUPPLIES, INC 15870 El Prado Rd Ste B, Chino, CA 91708 (951) 279-2289	MCKESSON www.mckesson.com/our-products (866) 625-2679	
MEDICAL PRODUCTS -HEALTHLINK 3611 Saint john Bluff Road South #1 Jacksonville, FLA 32224 (800) 638-2625	ADLIFE MEDICAL SUPPLY & EQUIP 11436 Artesia Blvd. #C Artesia, CA 90701 (562) 809-0281	
		AIRGAS www.airgas.com (866) 935-3370

SECTION	**Approval date:**	
Personnel	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Staff Qualifications	**Revision date:**	

POLICY:

All professional health care personnel shall have current California licenses and certifications and shall be qualified and trained for assigned responsibilities.

PROCEDURE:

I. HEALTH CARE LICENSE AND CERTIFICATION REQUIREMENTS

A. All medical professional licenses and certifications are current and issued from the appropriate agency to practice in California. Copies and/or lists of currently certified or credentialed personnel shall be readily available when requested by reviewers.

Medical Professional	License/Certification	Issuing Agency
Certified Nurse Midwife	RN License and Nurse-Midwife certificate	CA Board of Registered Nursing
Certified Radiological Technologist (CRT)	CRT Certificate	CA Department of Public Health (Radiological Branch)
Doctor of Osteopathy (DO)	Physician's & Surgeon's Certificate, DEA Registration	Osteopathic Medical Board of CA, Drug Enforcement Administration
Licensed Midwife (LM)	Midwifery License 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 with NP Certification and Furnishing Number	CA Board of Registration Nursing
Pharmacist (Pharm.D)	Pharmacist License	CA State Board of Pharmacy
Physician/Surgeon (MD)	Physician's & Surgeon's Certificate, DEA Registration	Medical Board of CA, Drug Enforcement Administration
Physician's Assistant (PA)	PA License	Physician Assistant Examining Committee / Medical Board of CA
Radiological Technician	Limited Permit	CA Department of Health Care Services (Radiological Branch)
Registered Dietician (RD)	RD Registration Card	Commission on Dietetic Registration
Registered Nurse (RN)	RN License	CA Board of Registered Nursing

II. IDENTIFICATION OF HEALTH CARE PRACTITIONERS

A. A health care practitioner shall disclose his or her name and practitioner's license status, as granted by the State of California, on a nametag with at least 18-point type. A health care practitioner in a practice or office, whose license is prominently displayed, may opt not to wear a nametag.

Note: It is unlawful for any person to use the title "nurse" in reference to himself or herself, in any capacity, except for an individual who is a registered nurse (RN) or licensed vocational nurse (LVN).

III. TRAINING OF SITE PERSONNEL

A. 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 supervisions, and knowledge of the available sources of information on site.

B. Provider and staff shall be able to demonstrate operation of medical equipment used in their scope of work.

Name Tags (Identification of Health Care Personnel)

680. (a) Except as otherwise provided in this section, a **health care practitioner shall disclose, while working, his or her name** and practitioner's license status, as granted by this state, **on a name tag in at least 18-point type. A health care practitioner in a practice or an office, whose license is prominently displayed, may opt to not wear a name tag.** If a health care practitioner or a 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 name tag requirement for individual safety or therapeutic concerns. **In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title "nurse" in reference to himself or herself and in any capacity, except for an individual who is a registered nurse or a licensed vocational nurse, or as otherwise provided in Section 2800.** Nothing in this section shall prohibit a certified nurse assistant from using his or her title.

Source: BUSINESS AND PROFESSIONS CODE SECTION 680-685

http://www.leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=00001-01000&file=680-685

Cal. Code Regs. tit. 22 § 73529

Section 73529 - Employee Name Badges

All personnel serving patients or the public shall wear name and title badges unless contraindicated.

https://casetext.com/regulation/california-code-of-regulations/title-22-social-security/division-5-licensing-and-certification-of-health-facilities-home-health-agencies-clinics-and-referral-agencies/chapter-4-intermediate-care-facilities/article-4-administration/section-73529-employee-name-badges

Licensing

The Board's Licensing Program protects consumers through proper licensing of physicians and surgeons and certain allied health care professionals.

Notice to Consumers

Per Business and Professions Code (BPC) section 2026, the Board was required to develop regulations to require its licentiates and registrants to provide notice to their clients or patients that the practitioner is licensed or registered in this state by the Board, that the practitioner's license can be checked, and that complaints against the practitioner can be made through the Board's Internet Web site or by contacting the Board.

In response to BPC section 2026, the Board amended Title 16 of the California Code of Regulations (CCR) section 1355.4 (applicable to physicians and surgeons) and section 1379.58 (applicable to polysomnographic technologists, technicians, and trainees.)

The Board also added 16 CCR section 1378.5 (applicable to research psychoanalysts) and section 1379.4 (applicable to licensed midwives).

Beginning **January 1, 2023**, all licensees and registrants of the Board must provide notice to each patient or client that they are licensed/registered and regulated by the Board, and their license/registration can be checked and complaints against the licensee/registrant can be made through the Board's website or by contacting the Board.

The notice shall include a quick response (QR) code that leads to the Board's Notice to Consumer webpage and shall contain the following statement and information:

Licensees/registrants may comply with this requirement by doing one of the following:

1. Post the notice in an area visible to patients/clients on the premises where the licensee/registrant provides the professional services in at least 38-point type in Arial font (sample signs are provided below);
2. Include the notice and an acknowledgement of receipt and understanding in a written statement in a language understood by the patient/client or their representative, signed and dated by the patient/client or their representative and retained in that patient's/client's medical records. The notice and acknowledgement of receipt and understanding may be provided and maintained in an electronic format (sample notices and acknowledgements of receipt and understanding are provided below); or
3. Include the notice in a language understood by the patient/client or their representative in a statement on letterhead, discharge instructions, or other document given to a patient/client or their representative, where the notice is placed immediately above the signature line for the patient/client in at least 14-point type.

The Board has posted the notice template with the QR code in the following languages on its Notice to Consumers webpage: English, Spanish, Chinese, Vietnamese, Tagalog, Korean, Armenian, Farsi, Arabic, Russian, Japanese, Punjabi, and Khmer.

If the licensee/registrant chooses to post a sign to comply with the notice requirement, and the sign is not in a language understood by the patient/client or their representative, then the notice must be provided under option 2 or 3 above, so long as the Board has provided a translated notice understood by the patient/client or their representative on its Notice to Consumers webpage.

A licensee/registrant will be deemed to be in compliance with this section if the hospital, clinic, or other practice location where they are practicing posts the notice on its premises in an area visible to patients/clients consistent with the requirements of the regulation.

Sample Signs for Posting:

- **Physicians and Surgeons:** English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer
- **Licensed Midwives:** English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer
- **Research Psychoanalysts:** English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer
- **Polysomnographic Technologists, Technicians, and Trainees:** English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer

Sample Notices and Acknowledgments of Receipt and Understanding:

- **Physicians and Surgeons:** English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer
- **Licensed Midwives:** English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer
- **Research Psychoanalysts:** English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer
- Polysomnographic Technologists, Technicians, and Trainees: English | Spanish | Chinese (Simplified) | Chinese (Traditional) | Vietnamese | Tagalog | Korean | Armenian (Eastern) | Armenian (Western) | Farsi | Arabic | Russian | Japanese | Punjabi (India) | Punjabi (Pakistan) | Khmer

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NOTICE TO PATIENTS

Medical doctors are licensed and regulated by the Medical Board of California.

To check up on a license or to file a complaint go to

www.mbc.ca.gov,

email: licensecheck@mbc.ca.gov,

or call (800) 633-2322.

1399.547. Notification to Consumers.

(a) A licensee engaged in providing medical services shall provide notification to each patient of the fact that the licensee is licensed and regulated by the board. The notification shall include the following statement and information:

NOTIFICATION TO CONSUMERS

Physician assistants are licensed and regulated

by the Physician Assistant Board

(916) 561-8780

www.pab.ca.gov

(b) The notification required by this section shall be provided by one of the following methods:

(1) Prominently posting the notification in an area visible to patients on the premises where the licensee provides the licensed services, in which case the notice shall be in at least 48-point type in Arial font.

(2) Including the notification in a written statement, signed and dated by the patient or the patient's representative and retained in that patient's medical records, stating the patient understands the physician assistant is licensed and regulated by the board.

(3) Including the notification in a statement on letterhead, discharge instructions, or other document given to a patient or the patient's representative, where the notice is placed immediately above the signature line for the patient in at least 14-point type.

Note: Authority cited: Section 3510, Business and Professions Code. Reference: Section 138, Business and Professions Code.

NOTIFICATION TO CONSUMERS REGULATION

Effective August 11, 2011, Section 1399.547, Title 16 of the California Code of Regulations, mandated by Business and Professions Code section 138, requires that physician assistants inform patients that they are licensed and regulated by the Physician Assistant Board. The notification must include the following statement and information:

NOTIFICATION TO CONSUMERS
PHYSICIAN ASSISTANTS ARE LICENSED AND REGULATED BY THE PHYSICIAN ASSISTANT BOARD
(916) 561.8780
WWW.PAB.CA.GOV

Physician assistants may provide this notification by one of the following three methods:

- Prominently posting a sign in an area of their offices conspicuous to patients, in at least 48-point type in Arial font.

- Including the notification in a written statement, signed and dated by the patient or patient's representative, and kept in that patient's file, stating the patient understands the physician is licensed and regulated by the Board.

- Including the notification in a statement on letterhead, discharge instructions, or other document given to a patient or the patient's representative, where the notification is placed immediately above the signature line for the patient in at least 14-point type.

For more information, please contact the Board at (916) 561.8780 or paboard@dca.ca.gov.

NOTIFICATION TO CONSUMERS

Physician Assistants are licensed and regulated by the Physician Assistant Board

(916) 561-8780

www.pab.ca.gov

SECTION	Approval date:	
Personnel	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Non-Physician Medical Practitioners	Revision date:	

POLICY:

All primary care provider (PCP) sites that employ non-physician medical providers (NPMP): Nurse Practitioners (NP), Certified Nurse Midwives (CNM), Licensed Midwives (LM), and/or Physician Assistants (PA), shall have standardized procedures (for LMs, NPs and CNM) and/or Practice Agreements/Delegation of Services Agreements (for PAs) that clearly define the scope of services and supervision.

The supervising physician is a physician and/or surgeon licensed by the Medical Board or by the Osteopathic Medical Board of California who supervises one or more physician assistants, possesses a current valid license to practice medicine, and is not currently on disciplinary probation for improper use of a physician assistant. “Supervision” means that a licensed physician and surgeon oversee the activities of, and accept responsibility for, the medical services rendered by a physician assistant. Physicians shall comply with all current and/or revised requirements established by the Medical Board of CA for supervising physician assistants. The supervising physician holds ultimate responsibility for the practice of each supervised non-physician medical practitioner.

PROCEDURE:

I. SCOPE OF PRACTICE OF NON-PHYSICIAN MEDICAL PRACTITIONERS

A. Nurse Practitioners, Certified Nurse Midwives shall have standardized procedures defining their scope of practice and supervision. Standardized procedures legally define the expanded scope of nursing practice that overlaps the practice of medicine. NPs and CNMs operate under written standardized Procedures that are collaboratively developed and approved by the supervising physician, the NP/CNM and administration within the organized health care facility/system in which standardized procedures will be used. Standardized procedures identify the furnishing of drugs or devices, extent of physician supervision, method of periodic review of competence, and review of provisions in the standardized procedures and must be dated and signed by the supervising physician and NP/CNM. All Standardized Procedures shall be readily accessible at all practice sites in which the NP or CNM works.

1. Nurse Practitioner (NP): Nurse practitioners may provide primary care and perform advanced procedures. The extent of required supervision must be specified in the standardized procedures.
2. Certified Nurse Midwife (CNM): The certificate to practice nurse mid-wifery authorizes the holder, under supervision of a licensed physician, 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 for the CNM shall be credentialed to perform obstetrical care in the same delivering facility in which the CNM has delivery privileges.

B. Physician Assistants shall have Practice Agreements/Delegation of Service Agreements defining their scope of practice and supervision. Practice Agreements/Delegation of Service Agreements defines specific procedures identified in practice protocols or specifically authorized by the supervising physician, and must be dated and signed by physician and PA. An original or copy must be readily accessible

at all practice sites in which the PA works. Failure to maintain a Practice Agreement/Delegation of Services Agreement is a violation of the Physician Assistant Regulations and is grounds for disciplinary action by the Medical Board of California against a physician assistant's licensure.

1. Delegation of Service Agreements (DSA): DSAs established prior to January 1, 2020 defines supervision responsibilities and methods required by Title 16, section 1399.545 of the Physician Assistant Regulations. The following procedures are identified:

    a. Transport and back-up procedures for when the supervising physician is not on the premises;
    b. One or more methods for performing medical record review by the supervising physician;
    c. Responsibility for physician review and countersigning of medical records; and
    d. Responsibility of the PA to enter the name of approved supervising physician responsible for the patient on the medical record

2. Practice Agreement: According to Senate Bill 697, starting January 1, 2020, newly established Practice Agreements shall define the supervision responsibilities and methods required by the Business and Professions Code, Sections 3502. The Senate Bill 697 removed the required supervisory procedures above under a DSA with the exception of the following: Transport and back-up procedures for when the supervising physician is not on the premises.

C. Standardized Procedures and Practice Agreements/Delegation of Service Agreements shall undergo periodic review every _____ year(s) to identify changes in the NPMP's scope of practice or other information. Standardized Procedures and Practice Agreements/Delegation of Service Agreements shall be revised, dated and signed whenever any changes occur.

D. The supervising physician delegates the supervision of Medical Assistants to NPMPs whenever the supervising physician is off premises.

E. Each NP, CNM, and PA that prescribes controlled substances is required to have a valid DEA Registration Number.

II. SUPERVISION OF NON-PHYSICIAN MEDICAL PRACTITIONERS

A. The supervising physician holds ultimate responsibility for the practice of each supervised non-physician medical practitioner. The supervising physician is permitted to supervise the following maximum number of NPMPs at any given time/shift in any of their locations:

- Four (4) Nurse Practitioners with furnishing licenses;
- Four (4) Certified Nurse Midwives; AND
- Four (4) Physician Assistants.

This may bring the total number of NPMPs supervised at any given time/shift/location to 12 (the ratio is unlimited for NPs who do not hold furnishing licenses). This ratio is based on each physician, not the number of offices. A primary care physician, an organized outpatient clinic or a hospital outpatient department shall utilize more NPMPs than can be supervised within these stated limits.

B. The supervising physician or designated back-up physician shall be available in person or by electronic communication at all times when a NPMP is caring for patients.

C. Evidence of supervision and measure of the NPMP(s) competence are completed using the following process(es) (check all that apply):

- Peer Review
- Clinical Competency Assessment
- Performance evaluation quality appraisal
- Routine medical record review of NPMPs documentation practice
- Routine tandem clinic rounds and case reviews
- Routine review of Standardized Procedures/Practice Agreements/DSA provisions
- Other (specify): _____

RESOURCES:

https://www.rn.ca.gov/faqs.shtml
https://www.rn.ca.gov/pdfs/regulations/npr-b-03.pdf
https://www.rn.ca.gov/pdfs/regulations/npr-b-20.pdf
https://www.rn.ca.gov/pdfs/regulations/npr-i-25.pdf
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200SB697
Notice to Consumers for Physicians and Physician Assistants
Notice to Consumers for Medical Doctors

Date: _____

To Whom It May Concern:

This is to certify that _____ has demonstrated and completed training as a “MEDICAL ASSISTANT” under the auspices of the undersigned as follows and in compliance with California Code of Regulations, Title 16, Chapter 13, Section 1366, 1366.1, 1366.2 and 1366.4:

A. Ten clock hours of training in administering injections and performing skin test.
B. Ten clock hours of training in venipuncture and skin puncture for the purpose of drawing blood.
C. Satisfactory performance of at least ten each of intramuscular, subcutaneous, and intradermal injections and ten skin tests, and/or at least ten venipunctures and ten skin punctures.
D. For those only administering mediation by inhalation, ten clock hours of training in administering medication by inhalation
E. Training in A-D above has included instruction and demonstration in:
    1. Pertinent Anatomy and Physiology appropriate to the procedure.
    2. Choice of equipment.
    3. Proper technique including sterile technique.
    4. Hazards and complications.
    5. Patient care following treatment or test.
    6. Emergency Procedure.
    7. California law and regulations for Medical Assistants.
F. Trained and has demonstrated, to the satisfaction of instructor, understanding purposes and technique of infection control.

In every instance, prior to administration of medicine by a medical assistant, a licensed physician or podiatrist, or another appropriate licensed person shall verify the correct medication and dosage. The supervising physician or podiatrist must authorize any technical supportive services performed by the medical assistant and that supervising physician or podiatrist must be physically present in the treatment facility when procedures are performed, except as provided in section 2069(a) of the code.

Sincerely yours,

_____

Physician Signature

Source: http://www.mbc.ca.gov/allied/medical_assistants_questions.html

SECTION	Approval date:	
Personnel	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Unlicensed Personnel	Revision date:	

POLICY:

All professional health care personnel shall be qualified and trained for assigned responsibilities.

PROCEDURE:

I. MEDICAL ASSISTANTS

A. Medical Assistants (MA) are unlicensed health personnel who perform basic *administrative, clerical, and non-invasive routine technical supportive services* under the supervision of a licensed physician. The licensed physician must be physically in the treatment facility during the performance of authorized procedures by the MA.

B. To administer medications by subcutaneous or intramuscular injection, or to perform intradermal skin tests, or venipunctures for withdrawing blood, an MA shall have completed at least the minimum number of training hours established in CCR, Title 16, Section 1366.1.

C. Training shall be administered under a licensed physician; or under a 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 shall be maintained on-site and include the following:

1. Diploma or certification from an accredited training program/school, or
2. 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. MEDICATION ADMINISTRATION

A. Unlicensed staff shall have evidence of appropriate training and supervision in all medication administration methods performed within their scope of work.

- The supervising physician shall specifically authorize all medications administered by an MA by means of a specific written or standing order prepared by the supervising physician.
- 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 simple injection.
- The pre-labeled medication container shall be shown to the licensed person prior to withdrawal of the medication from the container and administration.
- An MA may administer injections of scheduled drugs, including narcotic medications, only if the dosage is verified and the injection is intradermal, subcutaneous, or intramuscular.

- Medical assistants may not place an intravenous needle, start or disconnect the intravenous infusion tube, administer medications or injections into an intravenous line, or administer anesthesia.

III. MEDICAL EQUIPMENT

A. Personnel on site shall be qualified for their responsibilities and adequately trained for their scope of work. Site staff shall have a general understanding of the systems/processes in place, appropriate supervisions, and knowledge of the available sources of information on site.

B. Provider and staff shall be able to demonstrate operation of medical equipment used in their scope of work.

IV. IDENTIFICATION OF HEALTH CARE PRACTITIONERS

A. A health care practitioner shall disclose his or her name and the practitioner's license status, as granted by the State of California, on a nametag with at least 18-point type. A health care practitioner in a practice or office, whose license is prominently displayed, may opt not to wear a nametag.

Note: It is unlawful for any person to use the title "nurse" in reference to himself or herself, in any capacity, except for an individual who is a registered nurse (RN) or licensed vocational nurse (LVN).

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

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AN EXPLANATION OF STANDARDIZED PROCEDURE REQUIREMENTS FOR NURSE PRACTITIONER PRACTICE

Standardized Procedures are authorized in the Business and Profession Code, Nursing Practice Act (NPA) Section 2725 and further clarified in California Code of Regulation (CCR 1480). Standardized procedures are the legal mechanism for registered nurses, nurse practitioners to perform functions which would otherwise be considered the practice of medicine. Standardized procedures must be developed collaboratively by nursing, medicine, and administration in the organized health care system where they will be utilized. Because of this interdisciplinary collaboration for the development and approval, there is accountability on several levels for the activities to be performed by the registered nurse, nurse practitioner.

Organized health care systems includes health facilities, acute care clinics, home health agencies, physician's offices and public or community health services. Standardized procedures means policies and protocols formulated by organized health care systems for the performance of standardized procedure functions.

The organized health care system including clinics, physician's offices (inclusive of sites listed above) must develop standardized procedures permitting registered nurse, nurse practitioner to perform standardized procedure functions. A registered nurse, nurse practitioner may perform standardized procedure functions only under the conditions specified in a health care system's standardized procedure; and **must provide the system with satisfactory evidence that the nurse meets its experience, training, and/or education requirements to perform the functions.**

A nurse practitioner is a registered nurse who possesses additional preparation and skill in physical diagnosis, psycho-social assessment, and management of health-illness needs in primary health care, and who has been prepared in a program conforming to the Board standards as specified in CCR 1484 (Standards of Education).

The Board of Registered Nursing has set educational standards for nurse practitioner certification which must be met in order to "hold out" as a nurse practitioner. Nurse practitioners who meet the education standards and are certified by the BRN are prepared to provide primary health care, (CCR 1480 b), that which occurs when a consumer makes contact with a health care provider who assumes responsibility and accountability for the continuity of health care regardless of the presence or absence of disease.

Scope of Medical Practice

The Medical Practice Act authorizes physicians **to diagnose** mental and physical conditions, **to use drugs in or** upon human beings, **to sever or penetrate the tissue** of human beings and **to use other methods** in the treatment of diseases, injuries, deformities or other physical or mental conditions. As a general guide, the performance of any of these functions by a registered nurse, nurse practitioner requires a standardized procedure.

Standardized Procedure Guidelines.

The Board of Registered Nursing and the Medical Board of California jointly promulgated the following guidelines. (Board of Registered Nursing, Title 16, California Code of Regulations (CCR) section 1474; Medical Board of California, Title 16, CCR Section 1379.)

(a) Standardized procedures shall include a written description of the method used in developing and approving them and any revision thereof.

(b) Each standardized procedure shall:

(1) **Be in writing, dated and signed by the organized health care system** personnel authorized to approve it.

(2) Specify **which standardized procedure functions** registered nurses may perform and under what circumstances.

(3) State any specific **requirements which are to be followed** by registered nurses in performing particular standardized procedure functions.

(4) Specify any **experience, training, and/or education** requirements for performance of standardized procedure functions.

(5) Establish a method for initial and continuing **evaluation** of the competence of those registered nurses authorized to perform standardized procedure functions.

(6) Provide for a method of maintaining a written record of those **persons authorized to perform** standardized procedure functions.

(7) Specify the scope of **supervision** required for performance of standardized procedure functions, for example, telephone contact with the physician.

(8) Set forth any specialized circumstances under which the registered nurse is to immediately **communicate with a patient's physician** concerning the patient's condition.

(9) State the limitations on **settings**, if any, in which standardized procedure functions may be performed.

(10) Specify patient **record-keeping** requirements.

(11) Provide for a method of **periodic review** of the standardized procedures.

An additional safeguard for the consumer is provided by steps four and five of the guidelines which, together, form a **requirement that the nurse be currently capable** to perform the procedure. If a RN or NP undertakes a procedure without the competence to do so, such an act may constitute gross negligence and be subject to discipline by the Board of Registered Nursing.

Standardized procedures which reference textbooks and other written resources in order to meet the requirements of Title 16, CCR Section 1474 (3), must include book (specify edition) or article title, page numbers and sections. Additionally, the standards of care established by the sources must be reviewed and authorized by the registered nurse, physician and administrator in the practice setting. A formulary may be developed and attached to the standardized procedure. Regardless of format used, whether a process protocol or disease-specific, the standardized procedure must include all eleven required elements as outlined in Title 16, CCR Section 1474.

SUGGESTED FORMAT FOR STANDARDIZED PROCEDURES

I. POLICY

1. Function(s): (2)*
2. Circumstances under which R.N. may perform function: (2)
   a. Setting (9)
   b. Supervision (7)
   c. Patient Conditions
   d. Other

II. PROTOCOL (3)

1. Definitions
2. Data base
   a. Subjective
   b. Objective
3. Diagnosis
4. Plan
   a. Treatment
   b. Patient conditions requiring consultation (8)
   c. Education - patient/family
   d. Follow up
5. Record keeping (10)

III. REQUIREMENTS FOR REGISTERED NURSE: (4)(5)

1. Nurse practitioner education program, specialty
2. Advance level training
3. Experience as a nurse practitioner
4. National Certification in a specialty
5. Method of initial and continuing evaluation of competence

IV. DEVELOPMENT AND APPROVAL OF THE STANDARDIZED PROCEDURE

1. Method: (Title 16, CCR Section 1474(a))
2. Review schedule (11)
3. Signatures of authorized personnel approving the standardized procedure, and dates: (1)
   a. Nursing
   b. Medicine
   c. Administration

V. REGISTERED NURSES AUTHORIZED TO PERFORM PROCEDURE AND DATES (6)

1.
2.

*** Numbers in parentheses correspond to Board of Registered Nursing guideline numbers in Title 16, CCR Section 1474.**

EXAMPLE A (Process Protocol)

The Board of Registered Nursing does not recommend or endorse the medical management of this sample standardized procedure. It is intended as a guide for format purposes only.

Standardized Procedures

General Policy Component

I. Development and Review

A. All standardized procedures are developed collaboratively and approved by the Interdisciplinary Practice Committee (IDPC) whose membership consists of nurse practitioners, nurses, physicians, and administrators and must conform to all 11 steps of the standardized procedure guidelines as specified in Title 16, CCR Section 1474.

B. All standardized procedures are to be kept in a manual which includes dated, signed approval sheets of the persons covered by the standardized procedures.

C. All standardized procedures are to be reviewed every three years and as practice changes by the IDPC.

D. All changes or additions to the standardized procedures are to be approved by the IDPC accompanied by a dated and signed approval sheet.

II. Scope and Setting of Practice

A. Nurses may perform the following functions within their training specialty area and consistent with their experience and credentialing: assessment, management, and treatment of episodic illnesses, chronic illness, contraception, and the common nursing functions of health promotion, and general evaluation of health status (including but not limited to ordering laboratory procedures, x-rays, and physical therapies, recommending diets, and referring to Specialty Clinics when indicated).

B. Standardized procedure functions, such as managing medication regimens, are to be performed in (list area, i.e., short appointment clinic). Consulting physicians are available to the nurses in person or by telephone.

C. Physician consultation is to be obtained as specified in the individual protocols and under the following circumstances:

1. Emergent conditions requiring prompt medical intervention after initial stabilizing care has been started.

2. Acute decompensation of patient situation.

3. Problem which is not resolving as anticipated.

4. History, physical, or lab findings inconsistent with the clinical picture.

5. Upon request of patient, nurse, or supervising physician.

III. Qualifications and Evaluations

A. Each nurse performing standardized procedure functions must have a current California registered nursing license, be a graduate of an approved Nurse Practitioner Program, and be certified as a Nurse Practitioner by the California Board of Registered Nursing.

B. Evaluation of nurses' competence in performance of standardized procedure functions will be done in the following manner:

1. **Initial:** at 3 months, 6 months and 12 months by the nurse manager through feedback from colleagues, physicians, and chart review during performance period being evaluated.

2. **Routine:** annually after the first year by the nurse manager through feedback from colleagues, physicians, and chart review.

3. **Follow-up:** areas requiring increased proficiency as determined by the initial or routine evaluation will be re-evaluated by the nurse manager at appropriate intervals until acceptable skill level is achieved, e.g. direct supervision.

IV. Authorized Nurse Practitioners

List each

V. Protocols

The standardized procedure protocols developed for use by the nurses are designed to describe the steps of medical care for given patient situations. They are to be used in the following circumstances: management of acute/episodic conditions, trauma, chronic conditions, infectious disease contacts, routine gynecological problems, contraception, health promotion exams, and ordering of medications.

STANDARDIZED PROCEDURES FOR NURSE PRACTITIONERS

Revised Spring

Interdisciplinary Practice Committee

(signature) _____		(signature) _____	
full name & title	date	full name & title	date
(signature) _____		(signature) _____	
full name & title	date	full name & title	date
(signature) _____		(signature) _____	
full name & title	date	full name & title	date
(signature) _____		(signature) _____	
full name & title	date	full name & title	date

STANDARDIZED PROCEDURES

Management of Common Primary Care Conditions

I. Policy

A. As described in the General Policy Component.

B. Covers only those registered nurses as identified in General Policy Component.

II. Protocol

A. **Definition:** This protocol covers the management of common primary care conditions seen in the outpatient setting, such as eczema, headaches, acne, fatigue syndromes, allergic rhinitis, and low pain.

B. **Database** - Nursing Practice
(Perform usual total nursing assessment to establish data base).

C. **Treatment Plan** - Medical Regimen

1. **Diagnosis**
   a. Most consistent with subjective and objective findings expected by patient. If diagnosis is not clear, assessment to level of surety plus differential diagnosis.
   b. Assessment of status of disease process when appropriate.

2. **Treatment** - (Common nursing functions)
   a. Further lab or other studies as appropriate.
   b. Physical therapy if appropriate.
   c. Diet and exercise prescription as indicated by disease process and patient condition.
   d. Patient education and counseling appropriate to the disease process.
   e. Follow-up appointments for further evaluation and treatment if indicated.
   f. Consultation and referral as appropriate.

3. **Physician Consultation:** As described in the General Policy Component.

4. **Referral to Physician or Specialty Clinic:** Conditions for which the diagnosis and/or treatment are beyond the scope of the nurse's knowledge and/or skills, or for those conditions that require consultation.

5. **Furnishing Medications** - (Medical Regimen)
Follow furnishing protocol, utilizing formulary.

PROTOCOL: DRUGS AND DEVICES

Definition: This protocol covers the management of drugs and devices for women of all ages presenting to _____ clinic. The nurse practitioner may initiate, alter, discontinue, and renew medication included on, but not limited to the attached formulary. All Schedule I and Schedule II drugs are excluded.

Subjective Data: Subjective information will include but is not limited to:

1. Relevant health history to warrant the use of the drug or device.
2. No allergic history specific to the drug or device.
3. No personal and/or family history which is an absolute contraindication to use the drug or device.

Objective Data: Objective information will include but is not limited to:

1. Physical examination appropriate to warrant the use of the drug or device.
2. Laboratory tests or procedures to indicate/contraindicate use of drug or device if necessary.

Assessment: Subjective and objective information consistent for the use of the drug or device. No absolute contraindications of the use of the drug or device.

Plan: Plan of care to monitor effectiveness of any medication or device.

Patient Education: Provide the client with information and counseling in regard to the drug or device. Caution client on pertinent side effects or complications with chosen drug or device.

Consultation and/or Referral: Non-responsiveness to appropriate therapy and/or unusual or unexpected side effects and as indicated in general policy statement.

REFERENCES: PDR '94 50th Edition (list page)
Primary Care Medicine, 3rd Edition, Chapter (list), pp. (list)
Handbook of Gynecology and Obstetrics, 3rd Edition, Chapter (list), pp. (list)

FORMULARY

To include but not limited to those medications listed below:

Antibiotic: Ampicillin, Penicillin, Amoxicillin, Dicloxacillin, Augmentin, Keflex, Tetracycline, Noroxin, Minocin, Vibramycin, Benemid, Macrodantin, Erythromycin, Rocephin, Gantrisin, Trimethoprim/sulfamethoxazole, Nitrofurantoin, Nalidixic acid.

Antidiarrheal: Imodium, Donnagel

Antiemetic: Trans-derm V, Compazine, Phenergan, Tigan

Antifungal: Mycostatin oral suspension/tablets, Nizoral, Monistat, Femstat, Terazol, Gyne-Lotrimin

Antiviral: Zovirax ointment/capsules, Podophyllin 25-75%, Trichloroacetic acid

Antiparasite: Flagyl/Protostat, Kwell lotion/shampoo, RID lotion, Eurax cream

Biologic: RhoGAM, HypRho-D

Chemotherapeutic: 5FU for vaginal or vulvar use

Devices: Diaphragm, cervical cap, IUD, pessary, Norplant

Diuretic: Spironolactone, Dyazide

Hormone: All oral contraceptives, progesterone preparations, Estrogen (Premarin, Estinyl, Delestrogen, Estrovis, Estrace), Estraderm, Protestins (Aygestin, Provera, Micronor, Nor QD, Ovrette), Estrogen vaginal creams (Premarin, Estrace)

Local anesthetic: Xylocaine Jel 2%, Xylocaine 1% injection

Nonsteroidal Anti-inflammatory: Anaprox, Anaprox DS, Suprol, Motrin, Ponstel, Naprosyn, Rufen

Over the counter: Spermicidal agents, cold & cough preparations (non-narcotic), laxatives, stool softeners, antacids, antiflatulents, analgesics, prostaglandin inhibitors, topicals, vitamin/mineral, antihistamines, decongestants, hemorrhoidal/antidiarrheal.

Rectal:	Anusol HC, Wyanoids
Thyroid:	Synthroid, Armour thyroid tablets
Urinary analgesic:	Pyridium
Vaginal:	All appropriate antifungals, Aminocervical cream, Acijel, Betadine, Triple Sulfa cream, Estrogen cream.
Vitamin/Mineral:	Prenatal vitamins, iron pill

EXAMPLE B (Disease Specific)

The Board of Registered Nursing does not recommend or endorse the medical management of this sample standardized procedure. It is intended as a guide for format purposes only.

Standardized Procedures

DEPARTMENT:_____ FACILITY:_____

POLICY

I. FUNCTIONS NURSE PRACTITIONERS MAY PERFORM:

Provide care for patients with acute conditions as covered in attached protocol (see sample attached) and furnish non-controlled drugs and devices to essentially healthy patients.

II. CIRCUMSTANCES UNDER WHICH NURSE PRACTITIONERS MAY PERFORM THESE FUNCTIONS:

A. May furnish non-controlled drugs and devices under standardized procedures under the supervision of a designated physician (or designee).

B. Applies to nurse practitioners working in (indicate departments involved).

III. EXPERIENCE, TRAINING AND/OR EDUCATION REQUIRED OF THE NURSE PRACTITIONER:

Maintains a current California license to practice as an RN, is certified by the State of California as a Nurse Practitioner, has met all the requirements for and has a current Furnishing Number issued by the Board of Registered Nursing. Is oriented to the facility.

IV. METHOD OF INITIAL AND CONTINUED EVALUATION OF COMPETENCE:

General competency is initially evaluated during the probationary period through a proctoring process by the supervising physician. The registered nurse is assigned to and is supervised by a designated physician who is responsible to annually evaluate appropriateness of practice and clinical decision making. A QA review process is established to assure that compliance to standards relating to important aspects of care are maintained.

V. DOCUMENTATION

Documentation required is outlined in each protocol. Patient specific documentation is entered into the patient's medical record.

DEVELOPMENT AND APPROVAL OF THE STANDARDIZED PROCEDURE

I. THIS STANDARDIZED PROCEDURE WAS:

Developed by the supervising physician, or designee, and the Nurse Practitioner. Approved by the department Chief, Director of Nursing Practice, Physician-in-Chief or designees, and Medical Group Administrator.

II. THIS STANDARDIZED PROCEDURE WILL BE REVIEWED AT LEAST ANNUALLY.

REVISION DATED _____ REVIEWED DATED _____
_____ _____
_____ _____

III. THE STANDARDIZED PROCEDURE WAS APPROVED BY:

MEDICINE _____ DATE_____
(Chief of Department)

MEDICINE _____ DATE_____
(PIC/Designee)

NURSING _____ DATE_____
(Director of Nursing Practice)

ADMINISTRATION _____ DATE_____
(Medical Group Administrator)

IV. PRACTITIONERS FUNCTION UNDER THIS STANDARDIZED PROCEDURE:

Current list of authorized personnel are on file in the office of the Medical Group Administrator and department manager.

PROTOCOLS (List those applicable)

I.E., Urinary Tract Infection (see attached).
Respiratory tract infection
Otitis Media
Vaginitis

References: List

URINARY TRACT INFECTION PROTOCOL: INITIAL VISIT

I. RATIONALE

This protocol will assist in the differentiation between pyelonephritis and urinary tract symptoms sufficiently to eradicate the symptoms per se rather than attempt to eradicate any bacteriuria that may or may not be present. The design of the protocol for UTI encompasses these principles.

II. SYMPTOMS

A. CYSTITIS

1. FEMALE PATIENTS

Order a STAT CVMS UA for female patients with any of the following symptoms;

a. Dysuria
b. Frequency
c. Urgency
d. Inability to empty bladder completely

2. Male patients

Male patients with any of the above symptoms should be seen by an M.D., not by a NP, unless they have a urethral discharge (possible VD - follow VD protocol).

B. PYELONEPHRITIS

1. In addition to the above symptoms, patients with pyelonephritis may have:
   a. Fever greater than 100.0 F. or
   b. Flank pains, or
   c. Chills, or
   d. Nausea, vomiting or abdominal pain.
2. Continue with protocol through the physical exam with these patients, but then consult supervising physician before deciding on treatment.

III. HISTORY

A. Consult supervising physician if patient has:
   1. A history of kidney problems, or
   2. Is currently pregnant. To ascertain this, always ask for LMP date and record for all female patients.
   3. Diabetes or insulin.
   4. Three or more UTIs in past 12 months

B. Continue with UTI protocol, but also refer patient to GYN if history of:
   1. Vaginal discharge, or
   2. Perineal inflammation.

IV. PHYSICAL EXAM

A. Perform the following examinations:
   1. Abdominal
   2. CVA
   3. Temperature

B. Consult supervising physician if findings of:
   1. Fever greater than 100.0 F. or
   2. CVA tenderness.

V. LAB TESTS

INITIAL URINALYSIS

A. Consult supervising physician if:
   1. Casts
   2. RBCs or protein are positive (without associated WBC abnormality).

B. If UA shows 10 or more WBCs/hpf and patient is symptomatic, give patient antibiotic prescription as described in the treatment section.

C. If UA revealed 0-10 WBCs, review symptoms. If the symptoms are definite and very severe, treat with antibiotics; if symptoms are vague and poorly defined, then give patient symptomatic treatment as described in the treatment section and consider referral to GYN for pelvic.

D. Should the initial UA be "positive": (defined in guidelines below), then give patient a repeat UA slip for the abnormality found with instructions to have that UA one week following completion of treatment.

Positive UA findings are defined as:

Casts: any except occasional hyaline or rare granular
RBCs > 3 (if not menstruating) and WBC < 5
Protein > trace and WBC < 5

VI. TREATMENT

ANTIBACTERIAL TREATMENT

To be given if initial UA reveals 10 or more WBC/hpf, or in any case where symptoms are severe, even if UA revealed, WBC/hpf.

A. Prescribe appropriate antibiotic drug (see p.6)

B. Instruct patient to call in if symptoms do not subside within 72 hours. If patient does call back, information for treatment failure instructions.

SYMPTOMATIC TREATMENT

To be given only if initial UA reveals, 10WBC/Hpf, and patient has minimal or uncertain symptoms. Consider GYN referral for pelvic.

A. Prescribe either Propantheline 15 mg #20 sig: 1-2 QID prn or Belladonna with Pb tabs #15, sig: 1 tab QID prn.
B. Instruct patient to call in if symptoms persist beyond 72 hours or if symptoms worsen at any time.

VII. REPEAT URINALYSIS (CVMS)

A. Consult supervising physician if UA shows casts.
B. If repeat UA confirms abnormality (protein and/or RBC as listed below) refer to Proteinuria and/or Hematuria protocols.

Positive UA findings are defined as:
Casts: any, except occasional hyaline or rare granular
RBCs >3 (if not menstruating) and WBC <5
Protein > trace and WBC <5

UTC PROTOCOL: ANTIBIOTIC TREATMENT

A. If organism found in patient's urine is not listed in the table below, consult supervising physician for treatment.

B. If this is the first antibiotic course (initial visit), assume E coli and use the first listed drug to which patient is not allergic, as listed for E coli in the drug table below.

C. If this is a second antibiotic course (treatment failure), go to the first drug for the organism listed that is not the same as that previously used and to which the patient is not allergic. If the patient is allergic to all drugs listed, consult supervising physician for treatment.

D. Prescribe according to the prescription table which follows:

1. If symptoms have been present within the past 48 hours, use 1 dose treatment.
2. If symptoms have been present longer than 48 hours, use 5-day treatment.
3. If symptoms persists after treatment with first drug, repeat UA and culture and consult supervising physician.

UTI PROTOCOL: TREATMENT FAILURE

If the patient calls in with persisted or recurrent symptoms after the first course of antibiotic treatment, obtain a CVMS urine specimen for UA and culture and sensitivity.

If the UA is negative, wait for the culture results before treating. If the UA is positive, treat with the next drug listed on the Antibiotic Prescription Table and review treatment choice when the culture and sensitivity results are available.

If culture is positive and patients symptoms are improving, stay with the same antibiotic. If not responding after 3 days, switch to a new antibiotic based on culture sensitivity.

Adapted from protocol developed by: _____, NP

_____, MD

(List names of nurse practitioners and physicians who developed the standardized procedure, including the protocol section).

ANTIBIOTIC PRESCRIPTION TABLE

ORGANISM	DRUG
E. Coli Proteus mirabilis	Septra DS, Amoxicillin Macrodantin, Keflex
Aerobacter Klebsiella	Septra DS, Macrodantin Keflex, Ciprofloxacin
Enterococcus	Ampicillin *Consult MD if allergic
Pseudomonas	Ciprofloxacin (Usually not seen in out-patient setting)

DOSAGES

SEPTRA DS	#3 PO at once or 1 bid x 5 days
AMOXICILLIN	500mg 3gms PO at once or 250mg 1 tid x 5 days
MACRODANTIN	100mg qid x 5 days
KEFLEX	250mg qid x 5 days
CIPROFLOXACIN	250mg qid x 5 days

EXAMPLE C (Procedure Specific)

The Board of Registered Nursing does not recommend or endorse the medical management of this sample standardized procedure. It is intended as a guide for format purposes only.

Standardized Procedure for Dispensing by Registered Nurse

I. Policy

A. Drugs and devices listed in the agency formulary and prescribed by a lawfully authorized prescriber may be dispensed.
B. Setting - Adult Clinic.
C. Supervision - None required at the time of dispensing.

II. Protocol

A. Data Base
1. No patient or family history contraindications.
2. Agency required tests and procedures relative to the drug or device being dispensed demonstrate no contraindications.

B. Action
1. Affix label which contains information that follows.
a. Agency name, address and telephone number.
b. Patient's name.
c. Name of the prescriber and initials of the dispenser.
d. Date dispensed.
e. Trade or generic name of dispensed drug.
f. Quantity and strength of dispensed drug.
g. Directions for use of dispensed drug.
h. Expiration date of the drug's effectiveness.
2. Affix any appropriate auxiliary labels.
3. Use child proof containers.
4. Provide patient with appropriate information including:
- directions for taking the drug;
- what to do and whom to contact if side effects occur;
- common side effects;
- possible serious or harmful effects of the drug; and
- any manufacturer-prepared information required by the FDA.

C. Record Keeping - Document in the patient record:
1. Name, dosage, route and amount of the drug dispensed.
2. Lot number and manufacturer's name.
3. Other information, including patient instructions given.
4. Complete information in the pharmacy dispensing log.

D. Consultation - Contact the prescriber if the item is not listed in the agency formulary for RN dispensing or regarding contraindications.

III. Requirements for Registered Nurses

A. Education, training and experience: successful completion of the agency's in-service program on dispensing.

B. Initial evaluation: Demonstration of competency in skill performance to the satisfaction of the Pharmacy Director.

C. On-going evaluation - Monthly random record review by the pharmacist and an annual performance appraisal including observation of dispensing.

IV. Development and Approval of the Standardized Procedure

This standardized procedure was approved by the following:

NURSING_____ DATE _____

MEDICINE_____ DATE _____

PHARMACY_____ DATE _____

ADMINISTRATION _____ DATE _____

The standardized procedure will be reviewed annually.

V. RNs authorized to perform the procedure.

1. _____ DATE _____

2._____ DATE _____

Information Bulletin

SB 697 – Frequently Asked Questions

Overview

SB 697 (Chapter 707, Statutes of 2018) became effective on January 1, 2020 and made numerous changes to the Physician Assistant Practice Act (Act), which provides for licensure and regulation of physician assistants by the Physician Assistant Board (Board). Generally, the new law removes requirements that the medical record identify the responsible supervising physician and surgeon, removes requirements that the physician be physically available to the physician assistant for consultation, removes requirements for review and countersignature of patient medical records, and removes requirements that written guidelines for adequate supervision be established. The new law instead authorizes a physician assistant to perform medical services authorized by the Act if certain requirements are met, including that the medical services are rendered pursuant to a practice agreement, as defined, and the physician assistant is competent to perform the medical services.

The Act now requires that a practice agreement between a physician assistant and a physician and surgeon meet specified requirements, including that the agreement have policies and procedures to ensure adequate supervision of the physician assistant, including, but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the physician assistant in the provision of medical services. In addition, a practice agreement must establish policies and procedures to identify a physician and surgeon (with privileges to practice in that hospital) who is supervising a physician assistant rendering services in a general acute care hospital.

The prior law authorized a physician assistant, under the supervision of a physician and surgeon, to administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device, subject to specified requirements. The new law authorizes a physician assistant to furnish or order a drug or device subject to specified requirements, including that the furnishing or ordering be in accordance with the practice agreement and consistent with the physician assistant's educational preparation or for which clinical competency has been established and maintained, and that the physician and surgeon be available by telephone or other electronic communication method at the time the physician assistant examines the patient.

The Act now authorizes the physician assistant to furnish or order Schedule II or III controlled substances in accordance with the practice agreement or a patient-specific order approved by the treating or supervising physician and surgeon and requires completion of a controlled substances course by the PA's next renewal if the PA is

authorized by a practice agreement to furnish Schedule II controlled substances and if the PA has a DEA registration.

In addition, the new law provides that any reference to a "delegation of services agreement" in any other law means "practice agreement," as defined. The Act now provides that supervision does not require the supervising physician and surgeon to be physically present, but does require adequate supervision as agreed to in the practice agreement and does require that the physician and surgeon be available by telephone or other electronic communication method at the time the physician assistant examines the patient. However, the Act also prohibits this provision from being construed as prohibiting the Board from requiring the physical presence of a physician and surgeon as a term or condition of a PA's reinstatement, probation, or imposing discipline.

For more detailed information and to review the exact text of this new legislation, a copy of SB 697 is included with this information bulletin at:

http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200SB697.

The Board is providing the following information in response to questions received:

Practice Agreement

1. **What is a practice agreement?**

   The practice agreement replaces the delegation of services agreement. The practice agreement is a written agreement developed through collaboration among one or more physicians and surgeons ("physician") and one or more physician assistants (PA). The practice agreement defines the medical services the PA is authorized to perform pursuant to Business and Professions Code (BPC) section 3502 and grants approval for the physicians and surgeons on the staff of an "organized health care system"[1] to supervise one or more PAs in an organized health care system. (See BPC, § 3501, subd. (k).).

   The practice agreement must include provisions that address the following:

   (1) The types of medical services a physician assistant is authorized to perform,
   (2) Policies and procedure to ensure adequate supervision of the PA,
   (3) The methods for continuing evaluation of the competency and qualifications of the PA,

[1] Under the new law, an "organized health care system" includes a licensed clinic, an outpatient setting, a health facility, an accountable care organization, a home health agency, a physician's office, a professional medical corporation, a medical partnership, a medical foundation, and any other entity that lawfully provides medical services (see BPC, § 3501, subd. (j)).

(4) The furnishing or ordering of drugs or devices by a PA pursuant to Section 3502.1 (see answer to Question No. 5); and,
(5) Any additional provisions agreed to by the PA and the supervising physician. (See BPC, § 3502.3, subd. (a)(1).)

The practice agreement must be signed by the PA and one or more physicians or a physician who is authorized to approve the practice agreement on behalf of the staff of the physicians on the staff of an organized health care system. (See BPC, § 3502.3, subd. (a)(2).)

2. Will the Board be publishing a sample/template practice agreement on its website?

No, not at this time. Further, the law does not require the Board to approve practice agreements. (BPC, § 3502.3, subd. (a)(5).)

3. Can an existing delegation of services agreement be used instead of a practice agreement?

Yes. Any delegation of services agreement in effect prior to January 1, 2020 shall be deemed to meet the requirements of BPC Section 3502.3. (See BPC, § 3502.3, subd. (a)(3).)

4. **What Medical Services is a PA authorized to perform?**

A PA is authorized to perform those medical services described in the practice agreement. The PA must also have the competency to perform the medical services, and the PA's education, training, and experience must have prepared the PA to render the services. (See BPC, § 3502, subd. (a).)

Finally, in addition to any other practices that meet the criteria set forth in the Act or the Board's or the Medical Board of California's regulations, a practice agreement may authorize a PA to do any of the following:

(1) Order durable medical equipment, subject to any limitations set forth in Section 3502 of the Act (particularly competency, education training, and experience), or the practice agreement.

(2) For individuals receiving home health services or personal care services, after consultation with a supervising physician, approve, sign, modify, or add to a plan of treatment or plan of care.

(3) After performance of a physical examination by the PA under the supervision of a physician, certify disability pursuant to Section 2708 of the Unemployment Insurance Code. (See BPC, § 3502.3, subd. (b).)

Prescriptions

5. Are protocols and formularies for controlled substances required?

No. However, there are still criteria that need to be met to authorize a PA to furnish a controlled substance. A PA may furnish or order only those Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act that have been agreed upon in the practice agreement, and consistent with the PA's educational preparation or for which clinical competency has been established and maintained. With respect to Schedules II or III controlled substances, the practice agreement or a patient-specific order approved by the treating or supervising physician can authorize the PA to furnish a Schedule II or III controlled substance. (See BPC, § 3502.1, subds. (a), (d)(1), and (d)(2).)

A practice agreement authorizing a PA to order or furnish a drug or device shall specify all of the following:

(1) which PA or PAs may furnish or order a drug or device,
(2) which drugs or devices may be furnished or ordered,
(3) under what circumstances a drug or device will be furnished,
(4) the extent of physician supervision,
(5) the method of periodic review of the PA's competence, including peer review,
(6) review of the practice agreement (BPC, § 3502.1, subd. (b)(1); and,
(7) if the practice agreement authorizes the PA to furnish a Schedule II controlled substance, the practice agreement shall address the diagnosis of the illness, injury, or condition for which the PA may furnish the Schedule II controlled substance. (See BPC, § 3502.1, subd. (b)(2).)

To furnish any drug or device, the PA must have also completed a course in pharmacology that meets the requirements contained in section 1399.530 of Title 16 of the California Code of Regulations as that provision read on June 7, 2019. (See BPC, § 3502.1, subd. (e)(1).) For PAs that are authorized through a practice agreement to furnish Schedule II controlled substances, completion of a controlled substance education course is now mandatory, as described below.

6. Is the Controlled Substance Education Course required?

Yes. A PA who holds an active license, who is authorized through a practice agreement to furnish Schedule II controlled substances, who is registered with the U.S. Drug Enforcement Administration (DEA), and who has not completed a one-time course in compliance with sections 1399.610 and 1399.612 of Title 16 of the California Code of Regulations as those provisions read on June 7, 2019, shall complete, as part of their continuing education requirements, a course that

covers Schedule II controlled substances and the risks of addiction associated with their use, based on standards developed by the Board. Therefore, if a PA who holds an active license has not yet completed the required course, the PA needs to complete the course before renewing their license. (See BPC, § 3502.1, subd. (e)(3).)

7. Can a PA furnish or order Schedule II or III controlled substances?

Yes. A PA may furnish or order Schedule II or III controlled substances in accordance with the practice agreement or a patient-specific order approved by the treating or supervising physician. (See BPC, § 3502.1, subd. (d)(2).) However, continuing education and practice agreement requirements also need to be met to maintain compliance with the Act (see answers to Question Nos. 5 and 6 above).

8. Is supervising physician contact information required on PA prescriptions?

No. PA prescription pads are no longer required to list the name, address, and telephone number of their supervising physician. Further, a PA's drug order that is authorized to be issued under the Act must be treated in the same manner as a prescription of a supervising physician, and the signature of a PA on a drug order issued in accordance with the Act is deemed to be the signature of a prescriber for purposes of the Business and Professions Code and the Health and Safety Code. (See BPC, § 3502.1, subd. (g).)

<u>Supervision</u>

9. Are PAs required to identify their supervising physician for each episode of care in the patient's medical record?

Not anymore. The legislation removed the requirement that each episode of care for a patient identify the physician responsible for the supervision of the physician assistant. (See BPC, § 3502, as amended.)

10. Does the supervising physician still need to review or countersign my charts?

No. Unless the practice agreement requires it, the supervising physician no longer must review or countersign the medical records of a patient treated by a PA. The Board may, as a condition of probation or reinstatement of a licensee, require the review or countersignature of records of patients treated by a PA for a specified duration. (See BPC, § 3502, subd. (c).)

11. What are the Responsibilities of a Supervising Physician?

Under the new law, a supervising physician must provide adequate supervision of a PA as agreed to in the practice agreement. A supervising physician need not be physically present while the PA provides medical services but must be available by telephone or other electronic communication method at the time the PA examines the patient. (See BPC, § 3501, subd. (f)(1)(A)-(B).) However, the Board may require the physical presence of the supervising physician as a term or condition of a PA's reinstatement, probation, or imposing discipline. (See BPC, § 3501, subd. (f)(2).)

Supervision means that a physician oversees and accepts responsibility for the medical services provided by the PA. (See BPC, § 3501, subd. (f)(1).) While the PA is also no longer an agent of the supervising physician, the PA and the supervising physician can agree via practice agreement, that the PA is designated as an agent of the supervising physician. (See BPC, § 3502.3, subd. (a)(4).)

If rendering services in a general acute care hospital as defined in Health and Safety Code section 1250, the PA must be supervised by a physician who has privileges to practice in that hospital. Within a general acute hospital, the practice agreement shall establish policies and procedures to identify a physician who is supervising the PA. (See BPC, § 3502, subd. (f).)

However, amendments to the new law did not change the following requirements for physician supervision:

> (a) a physician assistant licensed by the board shall be eligible for employment or supervision by a physician who is not subject to a disciplinary condition imposed by the Medical Board of California prohibiting that employment or supervision.
>
> (b) Except as provided in Business and Professions Code section 3502.5 (state of war or emergency), a physician shall not supervise more than four physician assistants at any one time.
>
> (c) The Medical Board of California may restrict a physician and surgeon to supervising specific types of physician assistants including, but not limited to, restricting a physician and surgeon from supervising physician assistants outside of the field of specialty of the physician and surgeon. (See BPC, § 3516.)

Miscellaneous

12. Can a PA now own a majority share in a medical practice?

No. The new law did not change the Moscone-Knox Professional Corporation Act's ban on the owning of a majority of shares of a professional medical corporation. Under this prohibition a PA cannot own more than 49% of a professional medical corporation. (See Corp. Code, § 13401.5, subd. (a)(7).)

Form: PAB SB 697 FAQ Sheet .docx
Version: January 6, 2020

SECTION	Approval date:	
Personnel	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Personnel Training	Revision date:	

POLICY:

All staff at PCP sites shall receive education/training regarding safety issues, information on Members' rights and other issues related to clinical procedures. This education/training should take place initially upon hire, then annually thereafter for at least the specific topics identified below.

PROCEDURE:

I. NEW HIRE TRAINING

A. Upon hire, all new employees shall receive training on safety, members' rights and clinical procedures as outlined in the attached Safety and Member Rights Training Sign-In Sheet.
B. Types of training may include, but are not limited to new employee orientation; in-service training; instructional videos; educational materials; annual group training; self-paced learning modules; etc.
C. Upon completion of each topic within this education/training, the instructor/facilitator shall sign the Provider and Staff Education Checklist with the corresponding date of completion to acknowledge the participant's stated or demonstrated understanding of the education/training provided.
    - When all areas on the Provider and Staff Education Checklist have been completed, the personnel and the instructor/facilitator shall sign and date the Provider and Staff Education Checklist, formally acknowledging the personnel is knowledgeable of all criteria presented by the instructor/facilitator.
    - A copy of the completed Provider and Staff Education Checklist shall be kept in each employee's file. All records or education/training shall be kept for at least three years.

II. ANNUAL REVIEW

A. All personnel shall receive an annual training on at least the following site-specific topics: Infection Control, Blood Borne Pathogens Exposure Prevention and Biohazard Waste Handling.
B. Follow the same procedure as described above for new personnel.

ORIENTATION/STAFF TRAINING/CONTINUING EDUCATION

DATE: _____ INSERVICE/TRAINING DONE BY: _____

* **Annual Training Required**

Topics Discussed/Training and/or Information Provided
Fire Safety and Prevention
Emergency Non-Medical Procedure (e.g. site evacuation, workplace violence)
Medical Emergencies
Infection Control/Universal Precautions *
Blood Borne Pathogens Exposure Prevention *
Biohazardous Waste Handling *
Child/Elder/Domestic Violence Abuse
Patient Confidentiality
Informed Consent, including human sterilization
Prior Authorization Request; Health Plan Referral Process/Procedures/resources
Grievance/Compliant Procedure
Sensitive Services/Minor's Rights
Cultural and Linguistics
Disability Rights and Provider Obligations

Staff Name (Printed)	Title/Position Held	Signature

DISPOSITION OF PATIENTS WITH CONTAGIOUS DISEASES

Purpose: This is written to provide general guidelines for the treatment of a patient with a known or suspected communicable disease.

NOTE: Healthcare provider must recognize that any patient that presents with one of the following may be potentially infectious, and must take the necessary precautions to avoid secondary exposure. These precautions include following this protocol.

- · a skin rash
- · open wounds
- · blood or other body fluids
- · a respiratory illness that produces cough and/or sputum

Exposure Defined:
An exposure is determined to be any breach of the skin by cut, needle stick, absorption or open wound, splash to the eyes, nose or mouth, inhaled, and any other parenteral route.

- Patients with known or suspected communicable diseases/conditions calling in advance to schedule an appointment must be placed in a private room or with another patient who has an active infection with the same organism.

- Front desk staff will immediately notify the back office staff of the patient's arrival and request patient remains at desk until the medical assistant or nurse arrives to escort to the exam room.

- Gloves must be worn when entering the patient's room. Gloves should be changed after handling material that may have high concentrations of organisms. Gloves must be removed before leaving the patient's room and hands washed with an antimicrobial soap. Caregivers must ensure that hands do not touch potentially contaminated environmental surfaces after glove removal.

- Hand-washing should be done upon entering and exiting the exam room. Discard all disposable waste materials which have or may have come in contact with the patient in the trash container designated for biohazard waste.

- A gown/mask should be worn if substantial contact with the patient or environmental surfaces is anticipated or if the patient is incontinent, has diarrhea, an ostomy site, or other drainage not contained by a dressing. The gown/mask should be removed prior to leaving the room and care taken to avoid touching surfaces after removing the gown/mask.

- Non-critical patient care equipment should be used only for a single patient. If sharing of common equipment is absolutely necessary, the equipment must be adequately cleaned and disinfected before using it for another patient.

CLEANING AND DISINFECTION
Cleaning and Disinfection after a potentially contagious patient must be done immediately. Contaminated non-reusable equipment should be placed in biohazard bags and disposed of. Contaminated reusable patient care equipment should be placed in biohazard bags and labeled for cleaning and disinfection according to manufacturer's instruction.

Please Post

County of Los Angeles • Department of Public Health

County of Los Angeles Public Health

REPORTABLE DISEASES AND CONDITIONS

Title 17, California Code of Regulations (CCR), § 2500

It is the duty of every health care provider, knowing of or in attendance on a case or suspected case of any diseases or conditions listed below, to report to the local health officer for the jurisdiction where the patient resides. "Health care provider" encompasses physicians (surgeons, osteopaths, oriental medicine practitioners), veterinarians, podiatrists, physician assistants, registered nurses (nurse practitioners, nurse midwives, school nurses), infection control professionals, medical examiners/coroners, dentists, and chiropractors, as well as any other person with knowledge of a case or suspected case.

Urgency Reporting Requirements

☎ = Report **immediately** by telephone ✉ = Report within **1 working day** of identification ⑦ = Report within **7 calendar days** from time of identification

REPORTABLE DISEASES

⑦ Acquired Immune Deficiency Syndrome (AIDS) ■
✉ Amebiasis
⑦ Anaplasmosis/Ehrlichiosis
☎ Anthrax, human or animal ✚
✉ Babesiosis
☎ Botulism: infant, foodborne, or wound
⑦ Brucellosis, animal; except infection due to *Brucella canis* ✚
☎ Brucellosis, human ✚
✉ Campylobacteriosis
⑦ Chancroid ■
☎ Chickenpox (Varicella), only hospitalized and fatal cases, do **not** report cases of herpes zoster or shingles
⑦ *Chlamydia trachomatis* infection, including lymphogranuloma venereum (LGV) ■
☎ Cholera ✚
☎ Ciguatera Fish Poisoning
⑦ Coccidioidomycosis
⑦ Creutzfeldt-Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSE)
✉ Cryptosporidiosis
⑦ Cyclosporiasis
⑦ Cysticercosis or Taeniasis
☎ Dengue
☎ Diphtheria ✚
☎ Domoic Acid (Amnesic Shellfish) Poisoning
⑦ Ehrlichiosis/Anaplasmosis
✉ Encephalitis, specify etiology: viral, bacterial, fungal or parasitic
☎ *Escherichia coli*, shiga toxin producing (STEC) including *E. coli* O157 ✚
✉ Foodborne Disease
☎ Foodborne Outbreak; 2 or more suspected cases from separate households with same assumed source
⑦ Giardiasis
⑦ Gonococcal Infection ■
✉ *Haemophilus influenzae*, invasive disease only, less than 15 years of age
☎ Hantavirus Infection
☎ Hemolytic Uremic Syndrome
✉ Hepatitis A, acute infection
⑦ Hepatitis B, specify acute or chronic
⑦ Hepatitis C, specify acute or chronic
⑦ Hepatitis D (Delta), specify acute or chronic
⑦ Hepatitis E, acute infection
⑦ Human Immunodeficiency Virus (HIV) ■ (§2641-2643)
⑦ Influenza deaths, laboratory confirmed cases only, all ages ★
☎ Influenza, novel strains, human
⑦ Legionellosis
⑦ Leprosy (Hansen's Disease)
⑦ Leptospirosis
✉ Listeriosis ✚
⑦ Lyme Disease
✉ Malaria ✚
☎ Measles (Rubeola)
✉ Meningitis, specify etiology: viral, bacterial, fungal, or parasitic
☎ Meningococcal Infection
⑦ Mumps
☎ Paralytic Shellfish Poisoning
⑦ Pelvic Inflammatory Disease (PID) ■
✉ Pertussis (Whooping Cough)
☎ Plague, human or animal ✚
✉ Poliovirus Infection
✉ Psittacosis
✉ Q Fever
☎ Rabies, human or animal
✉ Relapsing Fever
⑦ Rickettsial Diseases (non-Rocky Mountain Spotted Fever), including Typhus and Typhus-like Illnesses
⑦ Rocky Mountain Spotted Fever
⑦ Rubella (German Measles)
⑦ Rubella Syndrome, Congenital
✉ Salmonellosis, other than Typhoid Fever ✚
☎ SARS (Severe Acute Respiratory Syndrome)
☎ Scabies, atypical or crusted ★
☎ Scombroid Fish Poisoning
☎ Shiga Toxin, detected in feces
✉ Shigellosis
☎ Smallpox (Variola)
✉ *Staphylococcus aureus* Infection; deaths only or admission to an intensive care unit of a person who: has not had surgery or dialysis or been hospitalized, or resided in a long-term care facility in the past year, and did not have an indwelling catheter or percutaneous medical device at the time of culture.
☎ Streptococcal Infection, outbreaks of any type
✉ Streptococcal Infection, individual case in a food handler or dairy worker
✉ Streptococcal Infection, Invasive Group A, including Streptococcal Toxic Shock Syndrome and Necrotizing Fasciitis; do **not** report individual cases of pharyngitis or scarlet fever. ★
⑦ *Streptococcus pneumoniae*, Invasive★
✉ Syphilis ■
⑦ Tetanus
⑦ Toxic Shock Syndrome
✉ Trichinosis
✉ Tuberculosis ✚ ■
⑦ Tularemia, animal
☎ Tularemia, human ✚
✉ Typhoid Fever, cases and carriers ✚
✉ *Vibrio* Infection ✚
☎ Viral Hemorrhagic Fevers, human or animal (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)
✉ West Nile Virus (WNV) Infection
☎ **Yellow Fever**
✉ Yersiniosis

☎ **OCCURRENCE OF ANY UNUSUAL DISEASE**

☎ **OUTBREAKS OF ANY DISEASE**, including diseases not listed above. Specify if occurring in an institution and/or the open community.

Reportable Non-Communicable Diseases or Conditions

⑦ Alzheimer's Disease and Related Conditions (CCR § 2802, § 2806, § 2810)
⑦ Disorders Characterized by Lapses of Consciousness (CCR § 2806, § 2810)
✉ Pesticide-Related Illnesses (Health and Safety Code §105200)

★ Reportable to the Los Angeles County Department of Public Health.
✚ Bacterial isolates and malarial slides must be forwarded to Los Angeles County Public Health Laboratory for confirmation. Health care providers must still report all such cases separately. ***Public Health Laboratory (562) 658-1300***
■ For questions regarding the reporting of HIV/AIDS, STDs or TB, contact the respective program:

HIV Epidemiology Program	***STD Program***	***TB Control Program***
(213) 351-8516	(213) 744-3070	(213) 745-0800
www.publichealth.lacounty.gov/hiv/index.htm	www.publichealth.lacounty.gov/std/index.htm	www.publichealth.lacounty.gov/tb/index.htm

To report a case or outbreak of any disease, contact the Communicable Disease Reporting System
Tel: (888) 397-3993 • Fax: (888) 397-3778

(Rev. 7/12)

COMMUNICABLE DISEASE PROTOCOL

Patients with communicable diseases will be **IMMEDIATELY** brought to a separate examination room, and are not permitted to remain in the waiting room.

A separate entrance should be used, if available.

Designated examination room is number _____

This room must remain closed with no admittance for at least one (1) hour after the patient leaves.

Safety&Health Fact Sheet

CONSULTATION CAL OSHA SERVICE

July 1999

Cal/OSHA Consultation Service
California Department of Industrial Relations
P. O. Box 420603 ▪ San Francisco, CA 94142-0603

Safety Needles & Needleless Systems

Bloodborne Pathogens Regulation Changes

New Cal/OSHA requirements intended to reduce needlesticks and other "sharps" injuries that can cause exposure to bloodborne pathogens took full effect on July 1, 1999. **An easy-to-read version of the revised regulation is available from the Cal/OSHA Consultation Service.**

Why was the regulation changed?

The recent changes to Section 5193 came about in response to:

- Continuing high numbers of needlestick and other sharps injuries in health care settings.
- Recognition of hepatitis C as a bloodborne pathogen of serious concern.
- Emerging technologies for needleless systems, and needles and other sharps devices with "engineered sharps injury protection" (e.s.i.p.).

Major elements of the revisions:

- New requirements for use of needleless systems and sharps devices with e.s.i.p., subject to four exceptions.
- New requirements for a program to evaluate and select needleless systems and sharps devices with e.s.i.p. appropriate for procedures conducted, with active involvement of frontline health care providers.
- Maintenance of a Sharps Injury Log.
- Addition of hepatitis C as a specifically named bloodborne pathogen.
- Reorganization of existing requirements for greater clarity, and a number of other changes.

Employers affected by these changes:

Health care providers continue to be the primary focus of Section 5193. The new requirements focus on employees conducting the following medical procedures:

- Withdrawal of body fluids.
- Accessing a vein or artery.
- Administration of medications or fluids.
- Any other procedure with potential for a sharps injury exposure incident.

Other employers who remain covered by the regulation include emergency and public safety services, correctional and custodial care facilities, and providers of services to any of these covered employers—such as plumbers and laundry—whose employees could be exposed to bloodborne pathogens. Employers whose employees may be reasonably anticipated to have occupational exposure to bloodborne pathogens are also covered, as are employees providing first aid.

What if safer devices are not available or could compromise patient care?

The goal of the new requirements is to protect employees without compromising patient safety or care. Practicing medical professionals helped draft the revisions. To address availability, patient care and other issues, there are four exceptions to the new requirements:

- Employer shows that no needleless systems or sharps devices with e.s.i.p. are available in the marketplace for their procedure.
- A licensed health care professional directly involved with a patient's care determines that available needleless systems or sharps devices with e.s.i.p. would compromise the patient's care or safety.
- Employer shows that available needleless systems and sharps devices with e.s.i.p. are not more effective in preventing exposure to bloodborne pathogens than the alternative they are using.
- Employer shows that sufficient information is not available on the safety performance of needleless systems or sharps devices with e.s.i.p. available in the marketplace, and the employer is actively evaluating such devices.

Where do we start?

Employers who have not yet begun converting to needleless systems and sharps devices with e.s.i.p. should focus **immediately** on coming into compliance by:

- Evaluating records of sharps injuries, talking with employees, and addressing areas where the frequency and consequences of exposure are greatest.
- Evaluating and selecting devices for the highest risk areas, then establishing the program—including maintenance of the required Sharps Injury Log—for all covered procedures.
- Documenting the above activities.

Cal/OSHA Consultation Service Offices

For telephone assistance and to request a no-cost consultation at your worksite:

Sacramento 916-263-0704
Oakland 510-622-2891
Van Nuys 818-901-5754
San Diego/San Bernardino/Anaheim 714-935-2750
Or toll-free **1-800-963-9424**

Questions asked frequently

Q. What does "engineeered sharps injury protection" (e.s.i.p.) mean?

A. As defined in the regulation, e.s.i.p. is a physical attribute that is built into a needle or other sharps device which effectively reduces the risk of a blood-borne pathogens exposure incident. Examples: devices which blunt, sheath, or withdraw the sharp.

Q. Would devices that facilitate safer recapping or disposal of sharps qualify as engineered sharps injury protection?

A. No. To qualify as e.s.i.p. the attribute must be an integral part of the sharps device. The ultimate intention, where any sharps device is used, is that it be guarded before—or as soon as possible after—removal from the patient or other source of blood or infectious material.

Q. Can I choose between a needleless system and a sharps device with e.s.i.p. if both are available for a particular procedure?

A. No. Where this choice is available, the needleless system must be used. Devices with e.s.i.p. are acceptable only where no satisfactory needleless system is available.

Q. Is a needleless system or sharps device with e.s.i.p. now required even when a doctor or nurse determines that it could compromise patient care or safety?

A. No. This is one of the exceptions to the new requirements. However, this exception is allowed only where a licensed health care professional directly involved in the patient's care has made and documented the determination, as required in the regulation.

Q. Can we use up our supply of traditional sharps devices?

A. Yes, but **only** where the required safer alternatives are not available, or one of the exceptions applies.

Q. We have completed our evaluation and selection process, including active involvement of affected employees, and have decided on the needleless system and sharps devices with e.s.i.p. that we want to use. However, our vendor has told us that several of the devices are temporarily out of stock. What do we do now?

A. Cal/OSHA recognizes that these major new requirements may cause temporary shortages of some devices, and will take this into account in enforcement actions. If the vendor delay is likely to be lengthy, alternative suppliers should be used. Just as with any device critical to continued patient care and employee safety, alternative devices and suppliers should be evaluated, selected and maintained as a back-up source.

Q. Is a device with engineered sharps injury protection that has been activated still required to be disposed of as sharps waste?

A. Yes. Because some devices can be defeated or deactivated, sharps with activated safety devices must still be disposed of as sharps waste.

Q. Do the new requirements apply to sharps other than needles?

A. Yes. The revised regulation contains a new definition of sharps in general, and requires that non-needle sharps be used which incorporate engineered sharps injury protection, subject to the four exceptions.

Q. Where can I get additional help with understanding the new requirements?

A. A number of Internet resources are listed below. You can also obtain free assistance from the Cal/OSHA Consultation Service without the concern of receiving an inspection or citations. You can request assistance by telephone, come into one of the offices around the state, or have a consultant come to your worksite.

Resources for information and assistance

Up-to-date information is key to keeping up with the requirements of Section 5193:

- At the Cal/OSHA website you can access a regulatory update which links to the new regulation: **www.dir.ca.gov/dosh**
- At the California Department of Health Services Sharps Program website—www.ohb.org/sharps.htm—you can see a list of needleless systems and sharps devices with e.s.i.p. and their manufacturers, and download a sample Sharps Injury Log.
- The federal OSHA website—www.osha.gov—has links to a wide variety of needlestick prevention resource materials.
- At the CDC website—www.cdc.gov—you can subscribe to Morbidity and Mortality Weekly Report by e-mail, and automatically receive recommendations of CDC, including for post-exposure procedures that are referenced by subsection (f) of Section 5193.
- The International Health Care Worker Safety Center (EPINet) website—www.med.virginia.edu/medcntr/centers/epinet/—has a wealth of information and resources, including a list of needleless systems and sharps devices with e.s.i.p., as well as detailed aggregate data on needlestick injuries recorded by the 70 institutions cooperating in its reporting network.
- The TDICT website—www.tdict.org—contains safety feature evaluation forms and other information to help with the process of evaluating and selecting safer devices.
- The Medical Waste Management Program in the California Department of Health Services has information on California requirements for management of medical waste. You can phone them at 916-327-6904.

Sharps Injury Log

Policy: To gather information related to occupational exposure to blood or other potentially infectious materials that may assist in developing new/improved systems for reducing/eliminating the risk of hazardous exposure.

Purpose: Sharps Injury Log is to generate a record of exposure incidents in the employer's facility that will include enough information about the cause of the incidents to allow the employer to analyze them and take preventive action.

California Code of Regulations, Title 8, Section 5193. Bloodborne Pathogens. Pathogens hazard from the workplace.

The employer shall establish and maintain a Sharps Injury Log, which is a record of each exposure incident involving a sharp. The exposure incident shall be recorded on the log within 14 working days of the date the incident is reported to the employer.

The information recorded shall include the following information, if known or reasonably available:

(A) Date and time of the exposure incident;
(B) Type and brand of sharp involved in the exposure incident;
(C) By July 1, 1999, a description of the exposure incident which shall include:

1. Job classification of the exposed employee;
2. Department or work area where the exposure incident occurred;
3. The procedure that the exposed employee was performing at the time of the incident;
4. How the incident occurred;
5. The body part involved in the exposure incident;
6. If the sharp had engineered sharps injury protection, whether the protective mechanism was activated, and whether the injury occurred before the protective mechanism was activated, during activation of the mechanism or after activation of the mechanism, if applicable;
7. If the sharp had no engineered sharps injury protection, the injured employee's opinion as to whether and how such a mechanism could have prevented the injury; and
8. The employee's opinion about whether any other engineering, administrative or work practice control could have prevented the injury.

Confidentiality. The employer shall ensure that employee medical records:

1. Kept confidential; and

2. Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

The Sharps Injury Log shall be maintained 5 years from the date the exposure incident occurred.

(A) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Chief and NIOSH for examination and copying.

(B) Employee training records required by this subsection shall be provided upon request for examination and copying to employees, to employee representatives, to the Chief, and to NIOSH.

(C) Employee medical records required by this subsection shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Chief, and to NIOSH in accordance with Section 3204.

(D) The Sharps Injury Log required by subsection (c)(2) shall be provided upon request for examination and copying to employees, to employee representatives, to the Chief, to the Department of Health Services, and to NIOSH.

Occupational Sharps Injury Log Addendum
(A Supplement to OSHA 300 and 301 Forms)

Insert your organization's confidentiality statement, instructions for completing log and obtaining medical care here.

Name of Employee_____ Employee ID Number_____

Assigned Injury ID #_____ Employee Work Unit_____

Date of Injury_____ Time of Injury_____ Completed by_____Date_____
(Employee health/ER staff)

Location of Injury (Check all that apply)	**Sharp Involved (If known)**	**Did the sharp being used have engineered injury protection(s)?**
☐ Finger ☐ Hand ☐ L ☐ R ☐ Arm ☐ L ☐ R ☐ Face or Head ☐ Torso ☐ Leg ☐ L ☐ R ☐ Other: _____ _____	Type: _____ Brand: _____ Model: _____ **Body Fluid Involved:** _____ _____ _____	☐ Yes ☐ No ☐ Don't Know **Was the protective mechanism activated?** ☐ Yes ☐ No ☐ Don't Know **When did the injury occur?** ☐ Before activation ☐ Don't Know ☐ During activation ☐ After activation

Job Classification	**Location and Department**	**Procedure**
☐ Doctor ☐ Nurse ☐ Intern/Resident ☐ Patient Care Support Staff ☐ Technologist: ☐ OR ☐ RT ☐ RAD ☐ Phlebotomist/Lab Tech ☐ Housekeeper/Laundry Worker ☐ Trainee, specify:_____ _____ ☐ Other:_____	☐ Patient Room ☐ ICU ☐ Outside Patient Room ☐ Emergency Department ☐ Operating Room/PACU ☐ Clinical Laboratory ☐ Outpatient Clinic/Office ☐ Utility Area ☐ Other:_____ _____ _____	☐ Draw venous blood ☐ Draw arterial blood ☐ Injection ☐ Start IV/Central line ☐ Heparin/Saline flush ☐ Obtain body fluid/tissue sample ☐ Cutting ☐ Suturing ☐ Other: _____ _____ _____

Describe, in detail, how the exposure incident occurred (e.g., the procedure being performed, the device being used, the body part affected, objects or substances involved and how they were involved):

_____
_____
_____
_____
_____
_____
_____
_____
_____

Note: Developed by the American Hospital Association. This is not an official OSHA form but is based on sharps injury documentation requirements found in OSHA's revised Bloodborne Pathogens Standard. These new requirements are in addition to OSHA's employee injury and incident reporting requirements (OSHA 300 and 301 forms).

OSHA® FactSheet

OSHA's Bloodborne Pathogens Standard

Bloodborne pathogens are infectious microorganisms present in blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), the virus that causes AIDS. Workers exposed to bloodborne pathogens are at risk for serious or life-threatening illnesses.

Protections Provided by OSHA's Bloodborne Pathogens Standard

All of the requirements of OSHA's Bloodborne Pathogens standard can be found in Title 29 of the Code of Federal Regulations at 29 CFR 1910.1030. The standard's requirements state what employers must do to protect workers who are occupationally exposed to blood or other potentially infectious materials (OPIM), as defined in the standard. That is, the standard protects workers who can reasonably be anticipated to come into contact with blood or OPIM as a result of doing their job duties.

In general, the standard requires employers to:

- **Establish an exposure control plan.** This is a written plan to eliminate or minimize occupational exposures. The employer must prepare an exposure determination that contains a list of job classifications in which all workers have occupational exposure and a list of job classifications in which some workers have occupational exposure, along with a list of the tasks and procedures performed by those workers that result in their exposure.
- **Employers must update the plan annually** to reflect changes in tasks, procedures, and positions that affect occupational exposure, and also technological changes that eliminate or reduce occupational exposure. In addition, employers must annually document in the plan that they have considered and begun using appropriate, commercially-available effective safer medical devices designed to eliminate or minimize occupational exposure. Employers must also document that they have solicited input from frontline workers in identifying, evaluating, and selecting effective engineering and work practice controls.
- **Implement the use of universal precautions** (treating all human blood and OPIM as if known to be infectious for bloodborne pathogens).
- **Identify and use engineering controls.** These are devices that isolate or remove the bloodborne pathogens hazard from the workplace. They include sharps disposal containers, self-sheathing needles, and safer medical devices, such as sharps with engineered sharps-injury protection and needleless systems.
- **Identify and ensure the use of work practice controls.** These are practices that reduce the possibility of exposure by changing the way a task is performed, such as appropriate practices for handling and disposing of contaminated sharps, handling specimens, handling laundry, and cleaning contaminated surfaces and items.
- **Provide personal protective equipment (PPE), such as gloves, gowns, eye protection, and masks.** Employers must clean, repair, and replace this equipment as needed. Provision, maintenance, repair and replacement are at no cost to the worker.
- **Make available hepatitis B vaccinations to all workers with occupational exposure.** This vaccination must be offered after the worker has received the required bloodborne pathogens training and within 10 days of initial assignment to a job with occupational exposure.
- **Make available post-exposure evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident.** An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM. This evaluation and follow-up must be at no cost to the worker and includes documenting the route(s) of exposure and the circumstances

under which the exposure incident occurred; identifying and testing the source individual for HBV and HIV infectivity, if the source individual consents or the law does not require consent; collecting and testing the exposed worker's blood, if the worker consents; offering post-exposure prophylaxis; offering counseling; and evaluating reported illnesses. The healthcare professional will provide a limited written opinion to the employer and all diagnoses must remain confidential.

- **Use labels and signs to communicate hazards.** Warning labels must be affixed to containers of regulated waste; containers of contaminated reusable sharps; refrigerators and freezers containing blood or OPIM; other containers used to store, transport, or ship blood or OPIM; contaminated equipment that is being shipped or serviced; and bags or containers of contaminated laundry, except as provided in the standard. Facilities may use red bags or red containers instead of labels. In HIV and HBV research laboratories and production facilities, signs must be posted at all access doors when OPIM or infected animals are present in the work area or containment module.
- **Provide information and training to workers.** Employers must ensure that their workers receive regular training that covers all elements of the standard including, but not limited to: information on bloodborne pathogens and diseases, methods used to control occupational exposure, hepatitis B vaccine, and medical evaluation and post-exposure follow-up procedures. Employers must offer this training on initial assignment, at least annually thereafter, and when new or modified tasks or procedures affect a worker's occupational exposure. Also, HIV and HBV laboratory and production facility workers must receive specialized initial training, in addition to the training provided to all workers with occupational exposure. Workers must have the opportunity to ask the trainer questions. Also, training must be presented at an educational level and in a language that workers understand.
- **Maintain worker medical and training records.** The employer also must maintain a sharps injury log, unless it is exempt under Part 1904 -- Recording and Reporting Occupational Injuries and Illnesses, in Title 29 of the Code of Federal Regulations.

Additional Information

For more information, go to OSHA's Bloodborne Pathogens and Needlestick Prevention Safety and Health Topics web page at: https://www.osha.gov/SLTC/bloodbornepathogens/index.html.

To file a complaint by phone, report an emergency, or get OSHA advice, assistance, or products, contact your nearest OSHA office under the "U.S. Department of Labor" listing in your phone book, or call us toll-free at **(800) 321-OSHA (6742)**.

This is one in a series of informational fact sheets highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999; the teletypewriter (TTY) number is (877) 889-5627.

For assistance, contact us. We can help. It's confidential.

OSHA®
Occupational Safety and Health Administration
www.osha.gov 1-800-321-6742

DSG 1/2011

Guideline for Hand Hygiene in Health-Care Settings published in 2002.

Information can be obtained at www.cdc.gov/handhygiene.

So Why All the Fuss About Hand Hygiene? *Most common mode of transmission of pathogens is via hands!*

• Clean hands are the single most important factor in preventing the spread of pathogens and antibiotic resistance in healthcare settings.
• Hand hygiene reduces the incidence of healthcare associated infections.
• CDC estimates that each year nearly 2 million patients in the United States get an infection in hospitals, and about 90,000 of these patients die as a result of their infection.
• More widespread use of hand hygiene products that improve adherence to recommended hand hygiene practices will promote patient safety and prevent infections.

Evidence of Relationship Between Hand Hygiene and Healthcare-Associated Infections

• There is substantial evidence that hand hygiene reduces the incidence of infections.
• Semmelweis demonstrated that the mortality rate among mothers who delivered in the First Obstetrics Clinic at the General Hospital of Vienna was significantly lower when hospital staff cleaned their hands with an antiseptic agent than when they washed their hands with plain soap and water.
• In general, adherence of healthcare workers to recommended hand hygiene procedures has been poor.

Self-Reported Factors for Poor Adherence with Hand Hygiene

Adapted from Pittet D, *Infect Control Hosp Epidemiol* 2000;21:381-386.

• Healthcare workers have reported several factors that may negatively impact their adherence with recommended practices including; hand washing agents cause irritation and dryness, sinks are inconveniently located, lack of soap and paper towels, not enough time, understaffing or overcrowding, and patient needs taking priority.
• Lack of knowledge of guidelines/protocols, forgetfulness, and disagreement with the recommendations were also self-reported factors for poor adherence with hand hygiene.
• Perceived barriers to hand hygiene are linked to the institution and HCWs colleagues. Therefore, both institutional and small-group dynamics need to be considered when implementing a system change to secure and improve HCWs hand hygiene practice.

Definitions

Hand hygiene
– Performing hand washing, antiseptic hand wash, alcohol-based hand rub, surgical hand hygiene/antisepsis
Hand washing
– Washing hands with plain soap and water
Antiseptic hand wash
– Washing hands with water and soap or other detergents containing an antiseptic agent
Alcohol-based hand rub
– Rubbing hands with an alcohol-containing preparation
Surgical hand hygiene/antisepsis
– Hand washing or using an alcohol-based hand rub before operations by surgical personnel
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Indications for Hand Hygiene

ƒ When hands are visibly dirty, contaminated, or soiled, wash with non- antimicrobial or antimicrobial soap and water.
ƒ If hands are not visibly soiled, use an alcohol-based handrub for routinely decontaminating hands.
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Specific Indications for Hand Hygiene

Before:
– Patient contact
– Donning gloves when inserting a CVC
– Inserting urinary catheters, peripheral vascular catheters, or other invasive devices that don't require surgery
After:
– Contact with a patient's skin
– Contact with body fluids or excretions, non- intact skin, wound dressings
– Removing gloves
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Selection of Hand Hygiene bAgents: Factors to Consider

• When evaluating hand hygiene products for potential use in healthcare facilities, administrators or product selection committees should consider the relative efficacy of antiseptic agents against various pathogens and the acceptability of hand hygiene products by personnel.

• Product acceptance can be affected by characteristics of the product such as its smell, consistency, color and the effect of skin irritation and dryness on hands.

• Easy access to hand hygiene supplies is essential for acceptance and use of products.

• Dispenser systems should function adequately and deliver an appropriate volume of product. Soap should not be added to a partially empty soap dispenser because of potential bacterial contamination of the soap.

Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Efficacy of Hand Hygiene Preparations in Killing Bacteria

• Plain soap is good at reducing bacterial counts but antimicrobial soap is better, and alcohol-based handrubs are the best.

Effect of Alcohol-Based Handrubs on Skin Condition

• Alcohol-based hand rubs are less damaging to the skin than soap and water.

• In the graph on the left the blue bar shows self-reported skin health scores for persons using soap and water, and persons using alcohol-based hand rubs are depicted by the orange bar. Self- reported studies indicate participants using soap and water reported a significant increase in dryness, cracking, and irritation after 2 weeks, whereas those that used the alcohol-based hand rub reported improvement in skin dryness.

• Epidermal water content shows the same results as the self-reported scores, after 2 weeks of use, the skin water content decreased for those that used soap and water (resulting in dryer skin) as compared with those who used an alcohol-based hand rub.

Boyce J, *Infect Control Hosp Epidemiol* 2000;21(7):438-441.

Time Spent Cleansing Hands:

one nurse per 8 hour shift

• The time required for nurses to leave a patient's bedside, go to a sink, and wash and dry their hands before attending the next patient is a deterrent to frequent hand washing or hand antisepsis.

• More rapid access to hand hygiene materials could help improve adherence.

• Alcohol-based hand rubs may be a better option than traditional hand washing with plain soap and water or antiseptic hand wash because they require less time, act faster, and irritate hands less often.

Voss A and Widmer AF, *Infect Control Hosp Epidemiol* 1997:18;205-208.

Recommended Hand Hygiene Technique

• These recommendations will improve hand hygiene practices of HCWs and reduce transmission of pathogenic microorganisms to patients and personnel in healthcare settings.

Handrubs

• When decontaminating hands with an alcohol-based hand rub, apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.

Handwashing

• When washing hands with soap and water, wet hands first with water, apply the amount of soap recommended by the manufacturer, and rub hands together for at least 15 seconds, covering all surfaces of the hands and fingers. Rinse hands with water, dry thoroughly with a disposable towel, and use the towel to turn off the faucet.

Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Surgical Hand Hygiene/Antisepsis

• Surgical hand hygiene (or antisepsis) can be performed by using either an antimicrobial soap OR an alcohol-based hand rub with persistent activity.

• When an antimicrobial soap is used, the hands and forearms should be scrubbed for the length of time recommended by the product's manufacturer, usually 2-6 minutes. Longer scrub times (e.g. 10 minutes) are usually not necessary.

• When an alcohol-based hand rub with persistent activity is used, follow the manufacturer's instructions on the amount of product to use. Pre-wash hands and forearms with a non-antimicrobial soap and allow them to dry completely. After application of the alcohol-based product as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves.

Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Fingernails and Artificial Nails

• Nail length is important because even after careful hand washing, HCWs often harbor substantial numbers of potential pathogens in the subungual spaces.
• Numerous studies have documented that subungual areas of the hand harbor high concentrations of bacteria, most frequently coagulase-negative staphylococci, gram-negative rods (including *Pseudomonas* spp.), corynebacteria, and yeasts.
• Natural nail tips should be kept to ¼ inch in length.
• A growing body of evidence suggests that wearing artificial nails may contribute to transmission of certain healthcare- associated pathogens. Healthcare workers who wear artificial nails are more likely to harbor gram-negative pathogens on their fingertips than are those who have natural nails, both before and after handwashing. Therefore, artificial nails should not be worn when having direct contact with high risk patients.
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Gloving

• Wearing gloves reduces the risk of healthcare workers acquiring infections from patients, prevents flora from being transmitted from healthcare workers to patients, and reduces contamination of the hands of healthcare workers by flora that can be transmitted from one patient to another.
• Gloves should be used when HCWs have contact with blood or other body fluids.
• Gloves should be removed after caring for a patient.
• The same pair of gloves should not be worn for the care of more than one patient.
• Gloves should not be washed or reused.
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Education/Motivation Programs

• One strategy to promote improved hand hygiene behavior is to monitor healthcare worker adherence with recommended hand hygiene practices and to give feedback.
• Strategies to improve adherence to hand hygiene practices should be both multimodal (i.e. use several different methods or strategies) and multidisciplinary (i.e. involve several different areas of the institution, and types of HCWs). Patients and their families can be involved in reminding HCWs to wash their hands.
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Administrative Measures to Improve Hand Hygiene

• Make improved hand hygiene an institutional priority and provide appropriate administrative support and financial resources.
• Several administrative measures may help improve hand hygiene adherence among personnel who work in areas where high workloads and high intensity of patient care are anticipated. These include placing alcohol-based handrubs at the entrance to patients' rooms, or at the bedside and providing healthcare workers with individual pocket-sized containers.
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Alcohol and Flammability

• Alcohols are flammable
• Alcohol-based handrubs should be stored away from high temperatures or flames
• Application is key: Let It Dry!
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Performance Indicators

• These performance indicators are recommended for measuring improvements in HCWs hand-hygiene adherence.
• Monitor and record adherence to hand hygiene by ward or service.
• Provide feedback to healthcare workers about their performance.
• Monitor the volume of alcohol-based hand rub used per 1,000 patient days.
• Monitor adherence to policies on wearing artificial nails.

Summary Alcohol-Based Hand rubs: What benefits do they provide?

• In summary, alcohol-based hand rubs provide several advantages compared with hand washing with soap and water, because they not only require less time, they also act faster. In addition, alcohol-based hand rubs are more effective for standard hand washing than soap, are more accessible than sinks, are the most efficacious agents for reducing the number of bacteria on the hands of healthcare workers, and can even provide improved skin condition.

PREVENTION IS PRIMARY!

Protect patients…protect healthcare personnel…promote quality healthcare!

Bio hazardous Waste

"Medical waste" means waste which meets both of the following requirements:

(1) The waste is composed of waste which is generated or produced as a result of any of the following actions:

(A) Diagnosis, treatment, or immunization of human beings or animals.

(B) Research pertaining to the activities specified in subparagraph (A).

(C) The production or testing of biological.

(D) The accumulation of properly contained home-generated sharps waste that is brought by a patient, a member of the patient's family, or by a person authorized by the enforcement agency, to a point of consolidation approved by the enforcement agency pursuant to Section 117904 or authorized pursuant to Section 118147.

(E) Removal of a regulated waste, as defined in Section 5193 of Title 8 of the California Code of Regulations, from a trauma scene by a trauma scene waste management practitioner.

(2) The waste is either of the following:

(A) Bio hazardous waste.

(B) Sharps waste.

(3) Waste also includes, but is not limited to:

(A) blood-soaked bandages

(B) culture dishes and other glassware

(C) discarded surgical gloves

(D) discarded surgical instruments

(E) discarded needles used to give shots or draw blood (e.g., medical sharps)

(F) cultures, stocks, swabs used to inoculate cultures

(G) removed body organs (e.g., tonsils, appendices, limbs)

(H) discarded lancets

"Bio hazardous waste" means any of the following:

A. Laboratory waste, including, but not limited to, all of the following:
   1. Human or animal specimen cultures from medical and pathology laboratories.
   2. Cultures and stocks of infectious agents from research and industrial laboratories.
   3. Wastes from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including Brucellosis and Contagious Ecthyma, as identified by the department, and culture dishes and de-vices used to transfer, inoculate, and mix cultures.

B. Human surgery specimens or tissues removed at surgery or autopsy, which are suspected by the attending physician and surgeon or dentist of being contaminated with infectious agents known to be contagious to humans.

C. Waste, which at the point of transport from the generator's site, at the point of disposal, or thereafter, contains recognizable fluid blood, fluid blood products, containers or equipment containing blood that is fluid, or blood from animals known to be infected with diseases which are highly communicable to humans.

D. Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans that are required to be isolated by the infection control staff, the attending physician and surgeon, or the local health officer, to protect others from highly communicable diseases that are highly communicable to humans.

Bio hazardous Waste Standard:
Containers may be of any color and shall be labeled with the words "Bio hazardous Waste" or with the international biohazard symbol and the word "BIOHAZARD" on the lid and on the sides so as to be visible from any lateral direction.

Bio hazardous Waste Handling Procedures:
Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

Bio hazardous Waste Storage:
A designated accumulation area used for the storage of medical waste containers prior to transportation or treatment shall be secured so as to deny access to unauthorized persons and shall be marked with warning signs on, or adjacent to, the exterior of entry doors, gates, or lids. The storage area may be secured by use of locks on entry doors, gates, or receptacle lids. The wording of warning signs shall be in English, "CAUTION—BIOHAZARDOUS WASTE STORAGE AREA—UNAUTHORIZED PERSONS KEEP OUT," and in Spanish, "CUIDADO—ZONA DE RESIDUOS—BIOLOGICOS PELIGROSOS—PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS," or in another language, in addition to English, determined to be appropriate by the infection control staff or enforcement agency. A warning sign concerning infectious waste, as that term was defined by Section 25117.5 as it read on December 31, 1990, that sign having been installed before April 1, 1991, meets the requirements of this section, until the sign is changed and as long as the sign is not moved. Warning signs shall be readily legible during daylight from a distance of at least 25 feet. Any enclosure or designated accumulation area shall provide medical waste protection from animals and natural elements and shall not provide a breeding place or a food source for insects or rodents.

Sharps Waste Handling Procedures:
Sharps Container "Sharps container" means a rigid puncture-resistant container that, when sealed, is leak resistant and cannot be reopened without great difficulty.

Sharps Waste "Sharps waste" means any device having acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, all of the following:

(a) Hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, syringes contaminated with bio hazardous waste, acupuncture needles, and root canal files.
(b) Broken glass items, such as Pasteur pipettes and blood vials contaminated with bio hazardous waste. (c) Any item capable of cutting or piercing that is contaminated with trauma scene waste.

To containerize sharps waste, a person shall do all of the following:

(a) Place all sharps waste into a sharps container.
(b) Tape closed or tightly lid full sharps containers ready for disposal to preclude loss of contents.
(c) Store sharps containers ready for disposal for not more than thirty days without the written approval of the enforcement agency.
(d) Label sharps containers with the words "sharps waste" or with the international biohazard symbol and the word "BIOHAZARD".

Source:
Medical Waste Management Act California Health and Safety Code Sections 117600 – 118360
www.cdph.ca.gov/.../**MedicalWaste/MedicalWasteManagementAct**
http://www.cdph.ca.gov/certlic/medicalwaste/Pages/default.aspx

OSHA® FactSheet

Personal Protective Equipment

Personal protective equipment, or PPE, is designed to protect workers from serious workplace injuries or illnesses resulting from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards. Besides face shields, safety glasses, hard hats, and safety shoes, protective equipment includes a variety of devices and garments such as goggles,coveralls, gloves, vests, earplugs, and respirators.

Employer Responsibilities

OSHA's primary personal protective equipment standards are in Title 29 of the Code of Federal Regulations (CFR), Part 1910 Subpart I, and equivalent regulations in states with OSHA-approved state plans, but you can find protective equipment requirements elsewhere in the General Industry Standards. For example, 29 CFR 1910.156, OSHA's Fire Brigades Standard, has requirements for firefighting gear. In addition, 29 CFR 1926.95-106 covers the construction industry. OSHA's general personal protective equipment requirements mandate that employers conduct a hazard assessment of their workplaces to determine what hazards are present that require the use of protective equipment, provide workers with appropriate protective equipment, and require them to use and maintain it in sanitary and reliable condition.

Using personal protective equipment is often essential, but it is generally the last line of defense after engineering controls, work practices, and administrative controls. Engineering controls involve physically changing a machine or work environment. Administrative controls involve changing how or when workers do their jobs, such as scheduling work and rotating workers to reduce exposures. Work practices involve training workers how to perform tasks in ways that reduce their exposure to workplace hazards.

As an employer, you must assess your workplace to determine if hazards are present that require the use of personal protective equipment. If such hazards are present, you must select protective equipment and require workers to use it, communicate your protective equipment selection decisions to your workers, and select personal protective equipment that properly fits your workers.

You must also train workers who are required to wear personal protective equipment on how to do the following:

- Use protective equipment properly,
- Be aware of when personal protective equipment is necessary,
- Know what kind of protective equipment is necessary,
- Understand the limitations of personal protective equipment in protecting workers from injury,
- Put on, adjust, wear, and take off personal protective equipment, and
- Maintain protective equipment properly.

Protection from Head Injuries

Hard hats can protect your workers from head impact, penetration injuries, and electrical injuries such as those caused by falling or flying objects, fixed objects, or contact with electrical conductors. Also, OSHA regulations require employers to ensure that workers cover and protect long hair to prevent it from getting caught in machine parts such as belts and chains.

Protection from Foot and Leg Injuries

In addition to foot guards and safety shoes, leggings (e.g., leather, aluminized rayon, or otherappropriate material) can help prevent injuries by protecting workers from hazards such as falling or rolling objects, sharp objects, wet and slippery surfaces, molten metals, hot surfaces, and electrical hazards.

Protection from Eye and Face Injuries

Besides spectacles and goggles, personal protective equipment such as special helmets or shields, spectacles with side shields, and faceshields can protect workers from the hazards of flying fragments, large chips, hot sparks,

optical radiation, splashes from molten metals, as well as objects, particles, sand, dirt, mists, dusts, and glare.

Protection from Hearing Loss

Wearing earplugs or earmuffs can help prevent damage to hearing. Exposure to high noise levels can cause irreversible hearing loss or impairment as well as physical and psychological stress. Earplugs made from foam, waxed cotton, or fiberglass wool are self-forming and usually fit well. A professional should fit your workers individually for molded or preformed earplugs. Clean earplugs regularly, and replace those you cannot clean.

Protection from Hand Injuries

Workers exposed to harmful substances through skin absorption, severe cuts or lacerations, severe abrasions, chemical burns, thermal burns, and harmful temperatureextremes will benefit from hand protection.

Protection from Body Injury

In some cases workers must shield most or all of their bodies against hazards in the workplace, such as exposure to heat and radiation as well as hot metals, scalding liquids, body fluids, hazardous materials or waste, and other hazards. In addition to fire-retardant wool and fireretardant cotton, materials used in whole-body personal protective equipment include rubber, leather, synthetics, and plastic.

When to Wear Respiratory Protection

When engineering controls are not feasible, workers must use appropriate respirators to protect against adverse health effects caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors. Respirators generally cover the nose and mouth or the entire face or head and help prevent illness and injury. A proper fit is essential, however, for respirators to be effective. Required respirators must be NIOSH-approved and medical evaluation and training must be provided before use.

Additional Information

For additional information concerning protective equipment view the publication, Assessing the Need for Personal Protective Equipment: A Guide for Small Business Employers (OSHA 3151) available on OSHA's web site at www.osha. gov. For more information about personal protective equipment in the construction industry, visit www.osha-slc.gov/SLTC/constructionppe/ index.html.

Contacting OSHA

To report an emergency, file a complaint or seek OSHA advice, assistance or products, call (800) 321-OSHA or contact your nearest OSHA regional or area office.

This is one in a series of informational fact sheets highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory impaired individuals upon request. The voice phone is (202) 693-1999; teletypewriter (TTY) number: (877) 889-5627.

For more complete information:

OSHA® Occupational Safety and Health Administration

U.S. Department of Labor

www.osha.gov

(800) 321-OSHA

DOC 4/2006

Cleaning Spills of Blood and Body Substances

- Wear protective gloves and use appropriate PPE (e.g., use forceps to pick up any sharps and discard in sharps container)
- If the spill contains large amounts of blood or body fluids (e.g., >10 mL), clean the visible matter with disposable absorbent material and discard in appropriate containers for biohazardous waste
- Decontaminate the area using an EPA-registered disinfectant with specific label claims for bloodborne pathogens (e.g., HIV, HBV, HCV) or a freshly diluted bleach-based product (preferably EPA-registered), in accordance with manufacturer's instructions, and allow the surface to dry
- If a bleach-based product is used:
  - Use a 1:100 dilution to decontaminate nonporous surfaces
  - If the spill involves large amounts of blood or body fluids, use a 1:10 dilution for first application of germicide *before cleaning*, then followed by cleaning and subsequent decontamination with 1:100 dilution application

Post-Exposure Evaluation and Management
Employers are required to establish exposure control plans that include post-exposure follow up for their employees and to comply with incident reporting requirements mandated by the 1992 OSHA bloodborne pathogen standard. Access to clinicians who can provide post-exposure care should be available during all working hours, including nights and weekends. HBIG, hepatitis B vaccine, and antiretroviral agents for HIV post-exposure prophylaxis (PEP) should be available for timely administration, either by providing access on site or by creating linkages with other facilities or providers to make them available off-site (CDC, 2001).

The following are recommendation by the Centers for Disease Control (DHHS, 2003) for immediate activity after exposure.

Provide immediate care to the exposure site.

- Wash wounds and skin with soap and water.
- Flush mucous membranes with water.
- Irrigate eyes with clean water, saline or sterile irrigants.

No scientific evidence shows that using antiseptics or squeezing the wound will reduce the risk of transmission of a bloodborne pathogen. Using a caustic agent such as bleach is not recommended.

Report the exposure to the government agency responsible for managing exposures. Reporting is necessary because PEP treatment may be recommended.

Spill Kit: Spray bottle with 10% bleach and water (1:10 solution). Label bottle with contents. Change bleach solution every 24 hours.

Zip Log Bag:

- 1 face mask
- 1 pair of goggles
- 1 pair of gloves
- 1 protective gown
- 1 copy of protocol

DECONTAMINATION PROCEDURES
BLOOD/BODY FLUID SPILLS

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. Decontamination includes procedures regulated by Health and Safety Code Section 118275.

Policy: To ensure the appropriate cleaning disinfecting of equipment and the patient care area to prevent the spread of infections.

Procedures:

1. All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials as soon as possible.

2. OSHA requires that work surfaces be cleaned with an "appropriate disinfectant." Appropriate disinfectants include a diluted bleach solution and EPA-registered antimicrobial products such as tuberculocides (List B), sterilants (List A), products registered against HIV/HBV (List E), and Sterilants/ High Level Disinfectants for equipment sterilization.
    - Fresh solutions of diluted household bleach made up every 24 hours are also considered appropriate for disinfection of environmental surfaces and for decontamination of sites. Contact time for bleach is generally considered to be the time it takes the product to air dry.

3. Employees must wear gloves when hand contact with blood, mucous membranes, OPIM, or non-intact skin is anticipated, and when performing vascular access procedures, or when handling contaminated items or surfaces [29 CFR 1910.1030(d)(3)(ix)].

4. Immediately clean-up of blood/body fluid spills as soon as possible after the spill occurs.

5. If the spill contains broken glass or other objects, these should be removed and discarded without contact with the hands. Use a device such as dustpan and broom to pick up sharp objects. Rigid sheets of cardboard may be used to handle such objects and discarded with the objects into an appropriate biohazard container.

6. Disinfect the spill site using an appropriate intermediate to high-level hospital disinfectant, such as a 10% dilution of household bleach. Flood the spill site or wipe down the spill site with disposable towels soaked in disinfectant to make the site. The disinfectant should be allowed to remain on the spill site for the period of time recommended by the manufacturer.

7. Wash hands as soon as possible after contamination and after removing gloves

8. If you get blood on you:
    - Wash it of as soon as possible with soap and water
    - Immediately flush your eyes with running water at a sink or eyewash station
    - Report the incident to your supervisor
    - Wear protective gloves
    - Disinfectant:
        - Solution of ¼ cup bleach per gallon of water
        - Commercially purchased disinfectant

CA Code of Regulations, Title 8, Sec. 5193
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051#1910.1030(d)(4)(ii)

Cleaning log

Cleaning and decontamination of equipment/work surfaces

Procedure:

1. All work surfaces and equipment must be cleaned with an approved disinfectant .

2. Clean work surfaces and/or equipment daily and before and after each patient use.

Directions:

Staff cleaning work surfaces and equipment shall initial the appropriate box (month and day). Staff shall initial and sign the bottom of this form for proper identification.

Location/area cleaned: _____ **Year:** _____

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1												
2												
3												
4												
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Staff signature/initials:

Print staff name: _____ Staff signature: _____ Initials: _____

Print staff name: _____ Staff signature: _____ Initials: _____

Print staff name: _____ Staff signature: _____ Initials: _____

Print staff name: _____ Staff signature: _____ Initials: _____

Print staff name: _____ Staff signature: _____ Initials: _____

SECTION	Approval date:	
Infection Control	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Sanitary Environment & Decontamination of Surfaces	Revision date:	

POLICY:

Site environment shall be maintained in a clean and sanitary condition. Environmental safety includes the hygienic condition of the site. The site shall follow decontamination procedures on contaminated surfaces according to Cal-OSHA Standards, 8 CCR §5193; CA H&S Code §118275. The site shall utilize products from the most current EPA approved product list and information available from the EPA, Antimicrobial Division's website at https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants

PROCEDURE:

I. General Appearance

A. Patient areas, restrooms, furniture, walls, floors, and carpets shall be unsoiled, neat, tidy, uncluttered, and in good repair.
   1. Cleaning shall be performed regularly, as scheduled, by staff or contracted service.
   2. Staff is responsible for keeping work areas neat and clean.
   3. Staff is responsible for reporting to the office manager/provider any soiled carpet, walls, etc. that require professional cleaning, repair, or replacement. Designated staff shall arrange for appropriate services, as needed.
   4. Staff is responsible for reporting to the office manager/provider if any equipment, furniture, carpet, etc. is in need of repair (i.e., torn upholstery covers, etc.). Designated staff shall arrange for repair or replacement, as needed.

II. Sanitary Supplies

A. Appropriate sanitary supplies shall be available for restroom use, including toilet tissue, hand washing soap, cloth/paper towels or antiseptic wipes.
B. Staff shall check restrooms frequently for presence of supplies and replenish supplies as necessary.

III. Hand Washing Facilities & Antiseptic Hand Cleaner

A. 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 is able to 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 wipes is acceptable until running water is available (29 CFR 1919.1030).

B. 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).

C. Antimicrobial agents or alcohol-based antiseptic hand rubs shall be 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.

IV. Routine Decontamination

A. Contaminated work surfaces are decontaminated with an appropriate disinfectant (29 CFR 1910.1030). Written "housekeeping" schedules have been established and are followed for regular routine daily cleaning. Staff is able to identify frequency for routine cleaning of surfaces and equipment, the disinfectant used and responsible personnel.

V. Disinfectant Products

A. Products used for decontamination have a current EPA-approved status. Product shall effectively kill HIV/HBV/TB. If manufacturer's product label indicates it will kill TB, it is understood that product will effectively kill HIV and HBV. Decontamination products are reconstituted and applied according to manufacturer's guidelines for "decontamination."

VI. 10% Bleach Solution

A. If 10% bleach solution is used (using a minimum of 5.25% sodium hypochlorite concentration), it 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) inactivating active ingredient, sodium hypochlorite. Surface is air dried or allowed appropriate time (stated on label) before wiping it dry and use. Manufacturer's directions, *specific* to every bleach product, are followed carefully.

VII. Waste Disposal Container

A. 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. (California Health and Safety Code Section 118275-118320) https://www.hercenter.org/rmw/osha-bps.php

B. Blood and Other Potentially Infectious Materials (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.

VIII. Spill Procedure

A. Staff is able to identify procedures for prompt decontamination of blood/body fluid spills, the Personal Protective Equipment (PPE) and disinfectant used, and the responsible person(s).

B. PPE for protection against bloodborne pathogen hazards is available on site and shall include: water repelling gloves; clothing barrier/gown; face/eye protection (e.g., goggles/face shield); and respiratory infection protection (e.g., mask). It does not include general work clothes (e.g., uniforms, cloth lab coats) that will permit liquid to soak through. General work clothes are appropriate only if blood/OPIM does not penetrate through employee's work clothes, undergarments, skin, eyes, mouth, or other mucous membranes under NORMAL conditions of use. The storage of PPE are 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.

SECTION	Approval date:	
Infection Control	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Infection Control / Standard and Universal Precautions	Revision date:	

POLICY:

Infection Control standards are practiced on site to minimize risk of disease transmission. Site personnel will 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, HCV, and other blood borne pathogens. "Universal precautions" refers to the OSHA mandated program that requires implementation of work practice controls, engineering controls, blood borne pathogen orientation/education, and record keeping in healthcare facilities.

PROCEDURE:

I. Hand Washing Facilities

A. 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 is able to 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 wipes is acceptable until running water is available (29 CFR 1919.1030).

B. Hand washing prevents infection transmission by removing dirt, organic material and transient microorganisms from hands. Hand washing with plain (non-antimicrobial) soap is acceptable for general patient care (Association for Professionals in Infection Control and Epidemiology, Inc., 1995).

II. Antiseptic Hand Cleaner

A. 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.

B. Hands shall be washed with soap and water when they are visibly soiled or after healthcare personnel have been in contact with patients with diarrheal illnesses such as Norovirus or *C. difficile*. As a precaution, wash with soap and water when in contact with any diarrheal illness.

III. Personal Protective Equipment (PPE)

A. PPE is specialized clothing and/or equipment for protection against blood borne pathogen hazards, and does not include general work clothes (e.g., uniforms, cloth lab coats) that permit liquid to soak through.

B. PPE is available for staff use on site, and includes,

- Water repelling gloves
- Clothing barrier (e.g., gown, sheets)
- Face/eye protection (e.g., goggles, face shield)
- Respiratory infection protection (e.g., mask)

C. Other necessary PPE are available specific to the practice and types of procedures performed on site. General work clothes are appropriate only if blood/OPIM does not penetrate through employee's work clothes, undergarments, skin, eyes, mouth, or other mucous membranes under NORMAL conditions of use.

D. 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.

IV. Contaminated Laundry

A. 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, linens and other reusable barriers. 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, linens and PPE are used on site.

V. Isolation Procedures

Personnel are able to demonstrate or verbally explain procedure(s) used on site to isolate patients with potentially contagious conditions from other patients.

A. Airborne precautions:
1. Have patient enter through a separate entrance to the facility (e.g., dedicated isolation entrance), if available, to avoid the reception and registration area;
2. Provide a facemask (e.g., procedure or surgical mask) to the patient and place them immediately in an airborne infection isolation room (AIIR);
3. If an AIIR is not available, place the patient immediately in an exam room with a closed door. If an AIIR is not available, place the patient immediately in an exam room with a closed door. Turn off air condition/heating equipment that may circulate the air from the isolation room into other patient areas within the facility;
4. Instruct the patient to keep the facemask on while in the exam room, if possible, and to change the mask if it becomes wet; and
5. Initiate protocol to transfer patient to a healthcare facility that has the recommended infection-control capacity to properly manage the patient;

6. PPE use:
    - Wear a fit-tested N-95 or higher level disposable respirator, if available, when caring for the patient; the respirator should be donned prior to room entry and removed after exiting room
    - If substantial spraying of respiratory fluids is anticipated, gloves and gown as well as goggles or face shield should be worn

7. Perform hand hygiene before and after touching the patient and after contact with respiratory secretions and/or body fluids and contaminated objects/materials;
8. Use soap and water when hands are visibly soiled (e.g., blood, body fluids);
9. Instruct patient to wear a facemask when exiting the exam room, avoid coming into close contact with other patients, and practice respiratory hygiene and cough etiquette;
10. Once the patient leaves, the exam room should remain vacant for generally one hour before anyone enters; however, adequate wait time may vary depending on the ventilation rate of the room and should be determined accordingly; and
11. If staff must enter the room during the wait time, they are required to use respiratory protection.

B. Droplet Precautions

1. Provide the patient with a facemask and place the patient in an exam room with a closed door as soon as possible (prioritize patients who have excessive cough and sputum production); if an exam room is not available, the patient is placed in a separate area as far from other patients as possible while awaiting care;
2. PPE use:
    - Wear a facemask, such as a procedure or surgical mask, for close contact with the patient; the facemask should be donned upon entering the exam room
    - If substantial spraying of respiratory fluids is anticipated, gloves and gown as well as goggles (or face shield in place of goggles) should be worn;
3. Perform hand hygiene before and after touching the patient and after contact with respiratory secretions and contaminated objects/materials; *note:* use soap and water when hands are visibly soiled (e.g., blood, body fluids);
4. Instruct patient to wear a facemask when exiting the exam room, avoid coming into close contact with other patients, and practice respiratory hygiene and cough etiquette; and
5. Clean and disinfect the exam room accordingly.

C. Contact Precautions

1. Apply to patients with any of the following conditions and/or disease:
    - Presence of stool incontinence (may include patients with Norovirus, rotavirus, or Clostridium difficile), draining wounds, uncontrolled secretions, pressure ulcers, or presence of ostomy tubes and/or bags draining body fluids
    - Presence of generalized or diffuse rash;
2. Prioritize placement of patients in an exam room if they have stool incontinence, draining wounds and/or skin lesions that cannot be covered, or have uncontrolled secretions;
3. Perform hand hygiene before touching patient and prior to wearing gloves;
4. PPE use:
    - Wear gloves when touching the patient and the patient's immediate environment or belongings
    - Wear a gown if substantial contact with the patient or their environment is anticipated;
5. Perform hand hygiene after removal of PPE; note: use soap and water when hands are visibly soiled (e.g., blood, body fluids), or after caring for patients with known or suspected infectious diarrhea (e.g., Clostridium difficile, Norovirus);
6. Clean/disinfect the exam room accordingly; and

7. Instruct patients with known or suspected infectious diarrhea to use a separate bathroom, if available. Clean/disinfect the bathroom before it can be used again.

VI. Waste Disposal Container

A. Contaminated wastes (e.g., dental drapes, bandages, sanitary napkins, soiled disposal 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.

B. Blood and Other Potentially Infectious Materials (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.

SECTION	Approval date:	
Infection Control	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Blood-Borne Pathogens and Biohazardous Waste Management	Revision date:	

POLICY:

The site will follow the OSHA Blood Borne Pathogens Standard and California Waste Management Act according to 8 CCR §5193 (Cal OSHA Health Care Worker Needle-stick Prevention Act, 1999); H&S Code, §§117600-118360 (CA Medical Waste Management Act, 1997); 29 CFR §1910, 1030.

PROCEDURE:

I. Blood and Other Potential Infectious Materials (OPIM)

A. 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.

II. Personal Protective Equipment (PPE)

A. PPE is specialized clothing and/or equipment for protection against blood borne pathogen hazards, and does not include general work clothes (e.g., uniforms, cloth lab coats) that permit liquid to soak through.

B. PPE is available for staff use on site, and includes,

- Water repelling gloves
- Clothing barrier (e.g., gown, sheets)
- Face/eye protection (e.g., goggles, face shield)
- Respiratory infection protection (e.g., mask)

C. Other necessary PPE are available specific to the practice and types of procedures performed on site. General work clothes are appropriate only if blood/OPIM does not penetrate through employee's work clothes, undergarments, skin, eyes, mouth, or other mucous membranes under NORMAL conditions of use.

D. 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.

III. Labels

A. 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 “BIOHAZARDOUS WASTE” label, (fluorescent orange or red-orange with contrasting lettering/symbols) is an integral part of the container or affixed to container. Sharps containers are labeled with 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. If the contaminated laundry or specimen leaves the site, an international “Biohazardous Waste” warning label and/or red color-coding is used.

IV. Needle-Stick Safety

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. Needleless systems, sharps with engineered sharps injury protection (ESIP), and non-needle sharps are used unless exemptions have been approved by Cal/OSHA (8CCR, §5193). Security of portable containers in patient care areas is maintained at all times. 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, leak-proof container. If these requirements are met, containers made of various materials (e.g., cardboard, plastic) are acceptable. Containers are not overfilled past manufacturer’s designated fill line, or more than three-quarters (¾) full. Supply of containers on hand is adequate to ensure routine change-out when filled.

V. Sharps Injury Documentation

Site has a method in place to document sharps injuries. Date, time, description of exposure incident, sharp type/brand, follow-up care is documented within 14 days of injury incident (see attached Sharps injury Report form).

VI. Contaminated Laundry

Site has a laundry service contract or a washer and dryer on site to launder contaminated laundry (soiled with blood/OPIM or containing contaminated sharps). Manufacturer’s guidelines are followed to decontaminate and launder reusable protective clothing. Laundry requirements are “not applicable” if only disposable PPE is used on site.

VII. Regulated Waste Storage

A. Regulated waste is contained separately from other wastes (e.g., contaminated wastes) at the point of origin in the producing facility, placed in red biohazardous bags with Biohazard label, and stored in a closed container that is not accessible to unauthorized persons. If stored outside of the office, a lock secures the entry door, gate or receptacle lid, and posted warning sign(s) in English and Spanish are visible for a distance of 25-feet. The sign wording states, "**CAUTION – BIOHAZARDOUS WASTE STORAGE AREA – UNAUTHORIZED PERSONS KEEP OUT"** and/or **"CUIDADO – ZONA DE RESIDUOS-BIOLOGICOS PELIGROSOS – PROHIBIDA LA ENTRADA A PERSONAS NO AUTHORIZADAS"**. Signs prior to the passage of the Medical Waste Act, Infectious Waste, are permitted for the "life" of the sign.

B. 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, and
   - Medical wastes, e.g., liquid/semi-liquid blood or OPIM, items caked with dry blood or OPIM and capable or releasing materials during handling, and contaminated sharps (Health and Safety Code, Chapter 6.1, CA Medical Waste Management Act).

VIII. Medical Waste Disposal

The method of medical waste disposal is as follows (check the method that applies):

☐ Medical waste are hauled to a permitted offsite medical waste treatment facility, to a transfer station, or to another registered generator for consolidation.

A limited-quantity exemption is not required for Small Quantity Generator (SQG - up to 35.2 pounds). For Large Quantity Generator (LQG - more than 35.2 pounds), hauling is done by a registered hazardous waste transporter or by a person with an approved limited-quantity hauling exemption granted by the CA DHS Waste Management Division. The limited-quantity hauling exemption is valid for a period of one year and is renewed annually. When hauling medical wastes, the LQG transporter carries the exemption form in the transporting vehicle. For both SQG and LQG, a medical waste tracking document is maintained that includes name of person transporting, number of waste containers, type of medical wastes, and date of transportation. Tracking document is kept a minimum of 3 years for LQG and 2 years for SQG.

☐ The medical building or hospital collects the medical waste from the clinic suite to a central accumulation area in the medical/hospital building where their contracted registered hauler picks up and hauls the waste for disposal.

☐ Other: _____
_____
_____

NOTE: Contaminated waste including materials soiled with blood or other body fluids/secretions that do not have the potential to be transmitted and infect others (e.g., dirty diapers, old bandages, etc.) are not within the scope of regulated waste. 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.

ATTACHMENTS:

Sharps Injury Report Form (resource)
Medical Waste Tracking Log (sample)
OSHA Fact Sheet - Protecting Yourself When Handling Contaminated Sharps

California Confidentiality of Medical Information Act
Medical Privacy Enforcement

California Office of Health Information Integrity
The enactment of AB 211 establishes the California Office of Health Information Integrity (CalOHII) to ensure the enforcement of state law mandating the confidentiality of medical information and to impose administrative fines for the unauthorized use of medical information. CalOHII may also recommend further action be taken by various agencies or entities to impose administrative fines, civil penalties, or other disciplinary actions against persons or entities that violate state confidentiality of medical information laws. AB 211 grants CalOHII the authority to adopt, amend, or repeal such rules and regulations as may be reasonable and proper to carry out the purposes and intent of the bill.

Health Care Provider Requirements
AB 211 requires providers of health care as defined to establish and implement appropriate administrative, technical, and physical safeguards to protect the privacy of a patient's medical information. AB 211 also requires providers of health care to reasonably safeguard confidential medical information from any unauthorized access or unlawful access, use or disclosure

Providers of Health Care Requirements
REQUIREMENTS TO COMPLY WITH AB 211 AND THE CMIA

AB 211 Compliance Requirements for Providers of Health Care (Health & Safety Code Division 109, section 130203(a)0

1. Every provider of health care as defined in Civil Code sections 56.05(j) shall establish and implement appropriate administrative, technical, and physical safeguards to protect the privacy of a patient's medical information.
   Every provider of health care as defined in Civil Code sections 56.05(j) shall reasonably safeguard confidential medical information from any unauthorized access or unlawful access, use or disclosure.

2. **Determining Compliance** (**Health & Safety Code Division 109, section 130203(b))**
   In determining if a violation has occurred, CalOHii will consider the provider's:
   - ⇒ Complexity
   - ⇒ Size
   - ⇒ History of compliance
   - ⇒ Steps taken to correct and prevent detected violations from reoccurring, and
   - ⇒ Any factors beyond the provider's control that restricted the facility's ability to comply.
   - ⇒ Implementing regulations will be promulgated by CalOHII in the future.

3. **Unauthorized Access Defined (**Health & Safety Code Division 109, section 130201(e) - Civil Code Division 1, Part 2.6, Ch.1, sections 56 et seq. (see especially section 56.10))
   Unauthorized access is the inappropriate viewing of patient medical information without direct need for diagnosis, treatment, or other unlawful use not permitted by either the Confidentiality of Medical information Act (CMIA) or any other laws governing the use or disclosure of medical information.
   For details on who must comply and penalties for violations, information is available on the following pages:
   - ⇒ Providers of Health Care Who Must Comply
   - ⇒ Penalties

HEALTH CARE PROVIDERS WHO MUST COMPLY (Health & Safety Code Division 2, sections 1200 et seq.)
A provider of health care as defined in Civil Code sections 56.05(j) and 56.06 must comply. Generally, sections 56.05(j) and 56.06 encompass three types of providers of health care: health care facilities, health care professionals, and businesses who maintain medical information. The following lists are the providers of health care who must comply referenced in Civil Code sections 56.05(j) and 56.06.
Civil Code Division 1, Part 2.6, Ch.1, sections 56.05(j) & 56.06
Civil Code section 56.05(j) refers to facilities licensed pursuant to Sections 1204, 1250, 1725, or 1745 of the Health and Safety Code:

- ⇒ Primary care clinics = Community clinics, Free clinics
- ⇒ Specialty clinics = Surgical clinics, Chronic Dialysis clinics, Rehabilitation clinics, Alternative Birth centers
- ⇒ General acute care hospitals Emergency centers
- ⇒ Acute psychiatric hospitals = Skilled nursing facilities, Intermediate care facilities, Special hospitals Congregate living health facilities, Correctional treatment centers, Home health agencies, Hospices, Mobile health care units

Civil Code section 56.05(j) also refers to health care professionals licensed under: Division 2 of the Business and Professions Code, Osteopathic Initiative Act, the Chiropractive Initiative Act, or any person certified pursuant to Division 2.5 of the Health and Safety Code: Acupuncturists, Chiropractors, Dentists, EMT I, EMT II, and Paramedics, Nurses, Occupational therapists, Opticians,

Optometrists, Osteopaths, Pharmacists, Physician and surgeons, Physician assistants, Physical therapists, Psychiatric technicians, Psychologists, Social workers, Therapists, Vocational nurses

Licensed professionals: Business & Professions Code Division 2, sections 500 et seq.
Osteopaths: Business & Professions Code Division 2, Ch.5, art.4, sections 2080-2099
Chiropractors: Business & Professions Code Division 2, Ch.2, art.1, sections 1000-1005
Emergency Medical Services: Health & Safety Code Division 2.5, sections 1797 et seq.

PENALTIES AND REFERRALS (CalOHII's authority: Civil Code Division 1, Part 2.6, Ch.1, sections 56.36(d) & (e), Health & Safety Code Division 109, sections 130202(a)(1) & (2), Penalties: Civil Code Division 1, Part 2.6, Ch.1, section 56.36(c))

Penalties

CalOHII may assess a penalty on providers of health care as defined in 56.05 (j) other than licensed facilities. Any administrative fine assessment by CalOHII for an unauthorized use, disclosure or access of individually identifying information will be in an amount as provided in Civil Code section 56.36. An administrative fine or civil penalty for any violation by a health care facility will be assessed by the California Department of Public Health.

a. CalOHII may assess penalties against health care professionals licensed under Division 2 of the Business and Professions Code, Osteopathic Initiative Act, the Chiropractive Initiative Act, or any person certified pursuant to Division 2.5 of the Health and Safety Code:
b. CalOHII may assess the following penalties: Providers of health care as defined, that knowingly and willfully violate a patient's medical information privacy are subject to penalties of up to:
    - ⇒ $2,500 for the first offense,
    - ⇒ $10,000 for the second offense,
    - ⇒ $25,000 for each subsequent offense.

Providers of health care as defined that violate a patient's medical information for financial gain are subject to penalties of up to:

- ⇒ $5,000 for the first offense,
- ⇒ $25,000 for the second offense,
- ⇒ $250,000 for each subsequent offense, and
- ⇒ Disgorgement of any proceeds.

Any person or entity, but not entities that are licensed facilities subject to California Department of Public Health oversight or Civil Code section 56.06 entities that negligently discloses medical information in violation of the CMIA, irrespective of damage, may be subject to an administrative fine of up to $2,500 per violation. (Civil Code Division 1, Part 2.6, Ch.1, section 56.36(c), Health & Safety Code Division 109, section 130202(a)(1))

c. When assessing a penalty, CalOHII shall consider any relevant circumstances including but not limited to the following:
    - ⇒ Good faith attempts to comply,
    - ⇒ Nature of the misconduct,
    - ⇒ Any harm done,
    - ⇒ Number of violations,
    - ⇒ Persistence of misconduct,
    - ⇒ Length of time over which the misconduct occurred,
    - ⇒ Willfulness of the misconduct, and
    - ⇒ Defendant's assets, liabilities, and net worth.

Civil Code Division 1, Part 2.6, Ch.1, section 56.36(d)

Referrals (Health & Safety Code Division 109, section 130205, Civil Code Division 1, Part 2.6, Ch.1, section 56.36(e))
The director of CalOHII may recommend to the Attorney General, district attorney, county counsel, city attorney, or city prosecutor that a civil action be brought under Civil Code section 56.36. In addition, the director of CalOHII may refer evidence of potential violations for discipline or further investigation to the relevant licensing authority who shall review all evidence submitted.

Source:
http://ohii.ca.gov/calohi/MedicalPrivacyEnforcement/ProvidersofHealthCareRequirements.aspx

CONFIDENTIALITY AGREEMENT

The Federal Health Insurance Portability Accountability Act (HIPAA) Privacy Law, the Confidentiality of Medical Information Act (California Civil Code - 56 et seq.) and the Lanterman-Petris-Short Act (California Welfare & Institutions Code - 5000 et seq.) govern the release of patient identifiable information by hospitals and other health care providers. The State Information Practices Act (California Civil Code sections 1798 et seq.) governs the acquisition and use of data that pertains to individuals. All of these laws establish protections to preserve the confidentiality of various medical and personal information and specify that such information may not be disclosed except as authorized by law or the patient or individual.

Confidential Patient Care Information includes: Any individually identifiable information in possession or derived from a provider of health care regarding a patient's medical history, mental, or physical condition or treatment, as well as the patients and/or their family members records, test results, conversations, research records and financial information. Examples include, but are not limited to:

- Physical medical and psychiatric records including paper, photo, video, diagnostic and therapeutic reports, laboratory and pathology samples;
- Patient insurance and billing records;
- Mainframe and department based computerized patient data and alphanumeric radio pager messages;
- Visual observation of patients receiving medical care or accessing services; and
- Verbal information provided by or about a patient.

Confidential Employee and Business Information include, but are not limited to, the following:

- Employee home telephone number and address;
- Spouse or other relative names;
- Social Security number or income tax withholding records;
- Information related to evaluation of performance;
- Other such information obtained from the University's records which if disclosed, would constitute an unwarranted invasion of privacy; or
- Disclosure of Confidential business information that would cause harm to Healthcare.

I understand and acknowledge that:

1. I shall respect and maintain the confidentiality of all discussions, deliberations, patient care records and any other information generated in connection with individual patient care, risk management and/or peer review activities.
2. It is my legal and ethical responsibility to protect the privacy, confidentiality and security of all medical records, proprietary information and other confidential information relating to Healthcare and its affiliates, including business, employment and medical information relating to our patients, members, employees and health care providers.
3. I shall only access or disseminate patient care information in the performance of my assigned duties and where required by or permitted by law, and in a manner which is consistent with officially adopted policies of Healthcare, or where no officially adopted policy exists, only with the express approval of my supervisor or designee. I shall make no voluntary disclosure of any discussion, deliberations, patient care records or any other patient care, peer review or risk management information, except to persons authorized to receive it in the conduct of Healthcare affairs.
4. Healthcare performs audits and reviews patient records in order to identify inappropriate access.
5. My user ID is recorded when I access electronic records and that I am the only one authorized to use my user ID. Use of my user ID is my responsibility whether by me or anyone else. I will only access the minimum necessary information to satisfy my job role or the need of the request.
6. I agree to discuss confidential information only in the work place and only for job related purposes and to not discuss such information outside of the work place or within hearing of other people who do not have a need to know about the information.
7. I understand that any and all references to HIV testing, such as any clinical test or laboratory test used to identify HIV, a component of HIV, or antibodies or antigens to HIV, are specifically protected under law and unauthorized release of confidential information may make me subject to legal and/or disciplinary action.
8. I understand that the law specially protects psychiatric and drug abuse records, and that unauthorized release of such information may make me subject to legal and/or disciplinary action.
9. My obligation to safeguard patient confidentiality continues after my termination of employment.

I hereby acknowledge that I have read and understand the foregoing information and that my signature below signifies my agreement to comply with the above terms. In the event of a breach or threatened breach of the Confidentiality Agreement, I acknowledge that the Physician's Office may, as applicable and as it deems appropriate, pursue disciplinary action up to and including my termination.

Print Name: _____ Signature: _____

Department: _____ Dated: _____

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Patient Confidentiality	Revision date:	

POLICY:

Confidentiality of personal medical information is protected according to state and federal guidelines. Patients have the right to privacy for dressing/undressing, physical examination, and medical consultation. Practices are in place to safeguard patient privacy. The patient's private health information shall be maintained secure and confidential in compliance with legal, accrediting and regulatory agency requirements. All member information is regarded as confidential and obtainable only to authorized persons.

PROCEDURE:

A. The primary care provider (PCP) site shall maintain confidentiality of individual patient information. Individual patient conditions or information not discussed in front of other patients or visitors, displayed or left unattended in reception and/or patient flow areas. Patient registration sign-in sheets protect patient's privacy from other patients who may also be checking-in for their appointments. Patient sign-in sheets shall collect only minimal information using no more than one (1) patient identifier such as the patient's name.

B. The PCP site shall ensure that exam rooms and dressing areas safeguard patient's right to privacy.

C. The provider/designee shall ensure that there is a system for the following:
   1. Medical records are available at each encounter and include outpatient, inpatient, referral services, and significant consultations.
   2. Medical records are accessible within the facility, or an approved health record storage facility on the facility premises.

D. Where applicable, electronic record-keeping system procedures are established to ensure patient confidentiality, prevent unauthorized access, authenticate electronic signatures, and maintain upkeep of computer systems. 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, idle monitor screen protection and blinded files.

E. The PCP site shall ensure that 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 will indicate to whom released and for what purpose. NOTE: The PCP site shall release and furnish necessary health records without the patient's written, signed consent to coordinate the patient's care with physicians, hospitals, or other health care entities, or to coordinate payment. PCPs shall also provide at no charge to health plans and appropriate state and federal regulators without written, signed consent from the patient, prompt access or upon demand, to medical records or information for quality management or other purposes, including utilization review, audits, reviews of complaints or appeals, HEDIS and other studies within 10 days of the request unless otherwise indicated or as agreed upon.

F. Transmittal of medical records by email shall be encrypted at all times. Transmission of medical records by fax shall include a fax cover page. The fax cover page includes a confidentiality statement which requires the recipient to maintain the information in a safe, confidential and secure manner and provide instructions on what steps to take when the transmittal is received by unintended recipients.

G. The PCP site shall ensure that medical records are retained for a minimum of 10 years following patient encounter.

H. The name of the individual delegated the responsible for securing & maintaining the security of medical records at this location is: _____

MEDICAL RECORD RELEASE AUTHORIZATION

PLEASE PRINT CLEARLY

PATIENT NAME: _____

ADDRESS: _____

PHONE #:_____BIRTHDATE: _____

1. I AUTHORIZE THE USE OR DISCLOSURE OF THE ABOVE NAMED INDIVIDUAL'S HEALTH INFORMATION AS DESCRIBED BELOW:
2. The following individual or organization is authorized to make the disclosure:
   Facility/Dr. Office Name: _____
   Address: _____
   Phone #: _____
3. For the purpose of review/examination and further authorize you to provide such copies of the records as may be requested. The foregoing is subject to such limitation as indicated below:
   _____ Entire Record _____ Substance Abuse
   _____ Psychiatric/Mental Health Information _____ HIV Information
   Specific Information: _____
4. This information may be disclosed to and used by the following individual or organization:
   Facility/Dr. Office Name: _____
   Address: _____
   Phone #: _____
   Reason for request: _____
5. I understand that I have a right to revoke this authorization at any time. I understand that if I revoke the authorization I must do so in writing and present my written revocation to the clinic. I understand that the revocation will not apply to information that has already been released in response to this authorization.
6. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to ensure treatment. I understand that I may inspect or copy the information to be used or disclosed, as provided in CFR 164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules.

   This authorization will automatically expire six (6) months from the date signed, unless otherwise indicated or revoked. I understand that I may revoke this consent at any time except to the extent that action has been taken in reasonable reliance upon the document.

_____

Signature of Patient or Legal Representative Date

_____

Signature of Witness Date

It is the policy of this medical practice that we will adopt, maintain, and comply with our Notice of Privacy Practices, which shall be consistent with HIPAA and California Law.

CALIFORNIA MINOR CONSENT AND CONFIDENTIALITY LAWS:
Minor Consent Services and Parents Access Rules*

MINORS OF ANY AGE MAY CONSENT	LAW	CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS
PREGNANCY	"A minor may consent to medical care related to the prevention or treatment of pregnancy," except sterilization. (Cal. Family Code § 6925).	The health care provider is not permitted to inform a parent or legal guardian without the minor's consent. The provider can only share the minor's medical information with parents with a signed authorization from the minor. (Cal. Health & Safety Code §§ 123110(a), 123115(a)(1); Cal. Civ. Code §§ 56.10, 56.11).
CONTRACEPTION	A minor may receive birth control without parental consent. (Cal. Family Code § 6925).	
ABORTION	A minor may consent to an abortion without parental consent. (Cal. Family Code § 6925; *American Academy of Pediatrics v. Lungren,* 16 Cal.4th 307 (1997)).	The health care provider is not permitted to inform a parent or legal guardian without the minor's consent. The provider can only share the minor's medical information with parents with a signed authorization from the minor. (*American Academy of Pediatrics v. Lungren,* 16 Cal.4th 307 (1997); Cal. Health & Safety Code §§ 123110(a), 123115(a)(1); Cal. Civ. Code §§ 56.10, 56.11).
SEXUAL ASSAULT[1] SERVICES [1]For the purposes of minor consent alone, sexual assault includes acts of oral copulation, sodomy, and other crimes of a sexual nature.	"A minor who [may] have been sexually assaulted may consent to medical care related to the diagnosis,…treatment and the collection of medical evidence with regard to the …assault." (Cal. Family Code § 6928).	The health care provider must attempt to contact the minor's parent/guardian and note in the minor's record the day and time of the attempted contact and whether it was successful. This provision does not apply if the treating professional reasonably believes that the parent/guardian committed the assault. (Cal. Family Code § 6928). Both rape and sexual assault of a minor are considered child abuse under California law and must be reported as such by mandated reporters. Health care providers are mandated reporters. The child abuse authorities investigating a child abuse report legally may disclose to parents that a report was made. See Cal. Penal § 11167 and 11167.5.
RAPE[2] SERVICES FOR MINORS UNDER 12 YRS[3] [2]Rape requires an act of non-consensual sexual intercourse. [3]See also "Rape Services for Minors 12 and Over" on page 2 of this chart	A minor under 12 years of age who may have been raped "may consent to medical care related to the diagnosis,…treatment and the collection of medical evidence with regard" to the rape. (Cal. Family Code § 6928).	

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MINORS OF ANY AGE MAY CONSENT	LAW	CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS
EMERGENCY MEDICAL SERVICES* *An emergency is "*a situation . . . requiring immediate services for alleviation of severe pain or immediate diagnosis of unforeseeable medical conditions, which, if not immediately diagnosed and treated, would lead to serious disability or death*" (Cal. Code Bus. & Prof. § 2397(c)(2)).	A provider shall not be liable for performing a procedure on a minor if the provider "reasonably believed that [the] procedure should be undertaken immediately and that there was insufficient time to obtain [parental] informed consent." (Cal. Bus. & Prof. Code § 2397).	The parent or guardian usually has a right to inspect the minor's records. (Cal. Health & Safety Code §§ 123110(a); Cal. Civ. Code § 56.10. *But see exception at endnote ([EXC.])).*
SKELETAL X-RAY TO DIAGNOSE CHILD ABUSE OR NEGLECT* * The provider does not need the minor's or her parent's consent to perform a procedure under this section.	"A physician and surgeon or dentist or their agents . . . may take skeletal X-rays of the child without the consent of the child's parent or guardian, but only for purposes of diagnosing the case as one of possible child abuse or neglect and determining the extent of." (Cal. Penal Code § 11171.2).	Neither the physician-patient privilege nor the psychotherapist-patient privilege applies to information reported pursuant to this law in any court proceeding.
MINORS 12 YEARS OF AGE OR OLDER MAY CONSENT	**LAW**	**CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS**
DIAGNOSIS AND/OR TREATMENT FOR INFECTIOUS, CONTAGIOUS COMMUNICABLE DISEASES	"A minor who is 12 years of age or older and who may have come into contact with an infectious, contagious, or communicable disease may consent to medical care related to the diagnosis or treatment of the disease, if the disease… is one that is required by law…to be reported…." (Cal. Family Code § 6926).	<u>RAPE and COMMUNICABLE DISEASES</u> The health care provider is not permitted to inform a parent or legal guardian without the minor's consent. The provider can only share the minor's medical information with parents with a signed authorization from the minor. (Cal. Health & Safety Code §§ 123110(a), 123115(a)(1); Cal. Civ. Code §§ 56.10, 56.11). <u>RAPE</u> Rape of a minor is considered child abuse under California law and mandated reporters, including health care providers, must report it as such. Providers cannot disclose to parents that they have made this report without the adolescent's authorization. However, adolescent patients should be advised that the child abuse authorities investigating the report legally may disclose to parents that a report was made.
RAPE SERVICES FOR MINORS 12 and OVER	"A minor who is 12 years of age or older and who is alleged to have been raped may consent to medical care related to the diagnosis or treatment of the condition and the collection of medical evidence with regard to the alleged rape." (Cal. Family Code 6927).	

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MINORS 12 YEARS OF AGE OR OLDER MAY CONSENT	LAW	CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS
OUTPATIENT MENTAL HEALTH SERVICES[4]/ SHELTER SERVICES [4]This section does not authorize a minor to receive convulsive therapy, psychosurgery or psychotropic drugs without the consent of a parent or guardian.	Two statutes give minors the right to consent to mental health treatment. If a minor meets the criteria under either statute, the minor may consent to his or her own treatment. If the minor meets the criteria under both, the provider may decide which statute to apply. There are differences between them. See endnote ** for more on these differences: <u>Family Code § 6924</u> "A minor who is 12 years of age or older may consent to mental health treatment or counseling on an outpatient basis or to residential shelter services, if both of the following requirements are satisfied: (1) The minor, in the opinion of the attending professional person, is mature enough to participate intelligently in the outpatient services or residential shelter services. AND (2) The minor (A) would present a danger of serious physical or mental harm to self or to others without the mental health treatment or counseling or residential shelter services, or (B) is the alleged victim of incest or child abuse." Cal. Family Code § 6924. <u>Health & Safety Code § 124260</u> "[A] minor who is 12 years of age or older may consent to [outpatient] mental health treatment or counseling services if, in the opinion of the attending professional person, the minor is mature enough to participate intelligently in the mental health treatment or counseling services." Health & Saf. Code § 124260.	<u>MENTAL HEALTH TREATMENT:</u> The health care provider is required to involve a parent or guardian in the minor's treatment unless the health care provider decides that such involvement is inappropriate. This decision and any attempts to contact parents must be documented in the minor's record. Cal. Fam. Code § 6924; 45 C.F.R. 164.502(g)(3)(ii). For services provided under Health and Safety Code § 124260, providers must consult with the minor before before deciding whether to involve parents. Health & Saf. Code § 124260(a). While this exception allows providers to inform and involve parents in treatment when appropriate, it does not give providers a right to disclose medical records to parents without the minor's consent. The provider can only share the minor's medical records with parents with a signed authorization from the minor. (Cal. Health & Saf. Code §§ 123110(a), 123115(a)(1); Cal. Civ. Code §§ 56.10, 56.11, 56.30; Cal. Welf. & Inst. Code § 5328. *See also endnote*([EXC]). <u>SHELTER:</u> Although minor may consent to service, the shelter must use its best efforts based on information provided by the minor to notify parent/guardian of shelter services.

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MINORS 12 YEARS OF AGE OR OLDER MAY CONSENT	LAW	CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS
DRUG AND ALCOHOL ABUSE TREATMENT • This section does not authorize a minor to receive replacement narcotic abuse treatment without the consent of the minor's parent or guardian. • This section does not grant a minor the right to refuse medical care and counseling for a drug or alcohol related problem when the minor's parent or guardian consents for that treatment. (Cal. Family Code § 6929(f)).	"A minor who is 12 years of age or older may consent to medical care and counseling relating to the diagnosis and treatment of a drug or alcohol related problem."(Cal. Family Code §6929(b)).	There are different confidentiality rules under federal and state law. Providers meeting the criteria listed under 'federal' below must follow the federal rule. Providers that don't meet these criteria follow state law. **FEDERAL**: Federal confidentiality law applies to any individual, program, or facility that meets the following two criteria: 1. The individual, program, or facility is federally assisted. (Federally assisted means authorized, certified, licensed or funded in whole or in part by any department of the federal government. Examples include programs that are: tax exempt; receiving tax-deductible donations; receiving any federal operating funds; or registered with Medicare.)(42 C.F.R. §2.12); **AND** 2. The individual or program: 1) Is an individual or program that holds itself out as providing alcohol or drug abuse diagnosis, treatment, or referral; **OR** 2) Is a staff member at a general medical facility whose primary function is, and who is identified as, a provider of alcohol or drug abuse diagnosis, treatment or referral; **OR** 3) Is a unit at a general medical facility that holds itself out as providing alcohol or drug abuse diagnosis, treatment or referral. (42 C.F.R. §2.11; 42 C.F.R. §2.12). For individuals or programs meeting these criteria, federal law prohibits disclosing any information to parents without a minor's written consent. One exception, however, is that an individual or program may share with parents if the individual or program director determines the following three conditions are met: (1) that the minor's situation poses a substantial threat to the life or physical well-being of the minor or another; (2) that this threat may be reduced by communicating relevant facts to the minor's parents; and (3) that the minor lacks the capacity because of extreme youth or a mental or physical condition to make a rational decision on whether to disclose to her parents. (42 C.F.R. §2.14). **STATE RULE**: Cal. Family Code §6929(c). Parallels confidentiality rule described under "Mental Health Treatment" *supra* at page 2. *See also exception at endnote* ([EXC]).

MINOR 12 YEARS OF AGE OR OLDER MAY CONSENT	LAW	CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS
AIDS/HIV TESTING AND TREATMENT	A minor 12 and older is competent to give written consent for an HIV test. (Cal. Health and Safety Code § 121020). A minor 12 and older may consent to diagnosis and treatment of HIV/AIDS. (Cal. Family Code § 6926).	The health care provider is not permitted to inform a parent or legal guardian without the minor's consent. The provider can only share the minor's medical information with parents with a signed authorization from the minor. (Cal. Health & Safety Code §§ 123110(a), 123115(a)(1); Cal. Civ. Code §§ 56.10, 56.11).
DIAGNOSIS AND/OR TREATMENT FOR SEXUALLY TRANSMITTED DISEASES	A minor 12 years of age or older who may have come into contact with a sexually transmitted disease may consent to medical care related to the diagnosis or treatment of the disease. (Cal. Family Code § 6926).	

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MINOR 15 YEARS OF AGE OR OLDER	LAW	CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS
GENERAL MEDICAL CARE	"A minor may consent to the minor's medical care or dental care if all of the following conditions are satisfied: (1) The minor is 15 years of age or older. (2) The minor is living separate and apart from the minor's parents or guardian, whether with or without the consent of a parent or guardian and regardless of the duration of the separate residence. (3) The minor is managing the minor's own financial affairs, regardless of the source of the minor's income." (Cal. Family Code § 6922(a)).	"A physician and surgeon or dentist may, with or without the consent of the minor patient, advise the minor's parent or guardian of the treatment given or needed if the physician and surgeon or dentist has reason to know, on the basis of the information given by the minor, the whereabouts of the parent or guardian." (Cal. Family Code § 6922(c). *See also exception at endnote (EXC)).*
MINOR MUST BE EMANCIPATED (GENERALLY 14 YEARS OF AGE OR OLDER)	**LAW**	**CONFIDENTIALITY AND/OR INFORMING OBLIGATION OF THE HEALTH CARE PROVIDER IN RELATION TO PARENTS**
GENERAL MEDICAL CARE for EMANCIPATED YOUTH	An emancipated minor may consent to medical, dental and psychiatric care. (Cal. Family Code § 7050(e)). *See* Cal. Family Code § 7002 for emancipation criteria.	The health care provider is not permitted to inform a parent or legal guardian without minor's consent. The provider can only share the minor's medical information with parents with a signed authorization from the minor. (Cal. Health & Safety Code §§ 123110(a), 123115(a)(1); Cal. Civ. Code §§ 56.10, 56.11).

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Endnotes:

***** There are many confidentiality and consent rules. Different rules apply in different contexts. This chart addresses the rules that apply when minors live with their parents or guardians. It does not address the rules that apply when minors are under court jurisdiction or in other special living situations. Further, the confidentiality section focuses on parent and provider access. It does not address when other people or agencies may have a right to access otherwise confidential information.

****** In addition to having slightly different eligibility criteria, there are other small differences between Health and Safety Code §124260 and Family Code § 6924. For example, the two laws both allow "professional persons" to deliver minor consent services but the two laws define "professional person" differently. Also, there is a funding restriction that applies to Health and Safety Code §124260 but not to Family Code § 6924. See Cal. Family Code 6924, Health & Saf. Code § 124260 and Welf. & Inst. Code § 14029.8 and look for more information on www.teenhealthlaw.org.

EXC: Providers may refuse to provide parents access to a minor's medical records, where a parent normally has a right to them, if "the health care provider determines that access to the patient records requested by the [parent or guardian] would have a detrimental effect on the provider's professional relationship with the minor patient or the minor's physical safety or psychological well-being." Cal. Health & Safety Code § 123115(a)(2). A provider shall not be liable for any good faith decisions concerning access to a minor's records. Id.

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GENERAL CONSENT TO TREAT – ADULT

Definitions: Every competent adult has the fundamental right of self-determination over his/her body and property.

> A **competent** adult has the ability to understand the nature and consequences of proposed health care, including its significant benefits, risks, and alternatives, and to make and communicate a health care decision.

California law imposes a duty on the patient's physician to secure the patient's informed consent for a complex procedure.*

Informed consent is not required for the performance of "simple and common" procedures where the related risks are commonly understood.

Purpose: To insure that an adult with capacity has the right to make his/her own decisions. (Probate Code Section 4670)

Individuals (incompetent adults) who are unable to exercise this right have the right to be represented by another (legal representative) who will protect their interest and preserve their basic rights.

Procedure:

1. A General Consent to Treat an Adult may be obtained at the discretion of the physician.

2. The General Consent to Treat an Adult is to be signed at the initial encounter by the patient or his/her legal representative.

3. The signed General Consent to Treat an Adult form is to be placed in the patient's medical record.

4. It is recommended that the General Consent to Treat an Adult be witnessed. All witnesses shall be 21 years of age or older. The witness shall be present when the patient/legal representative signs the form. The witness shall indicate that he/she witnessed the signing by placing his/her signature in the designated space on the form.

5. If the patient or the patient's legal representative has validly exercised his/her right to refuse to sign a General Consent to Treat form, the patient's wishes are to be respected. Treatment of the patient is the performed at the discretion of the physician.

6. In the case of medical emergency, treatment may proceed without the patient's (legal representative) consent if no evidence exists to indicate that the patient or legal representative would refuse treatment.

***Cobbs v. Grant, 8 Cal.3d229 (1972)**

_____
(Physician's Name)

_____
(Address)

_____
(Address)

Patient Name: _____

DOB: _____

Medical Record #: _____

INFORMED CONSENT

I, _____ authorize Dr. _____
(Print name of patient) (Print name of physician / surgeon)

to perform the surgery/procedure described as _____.

I have been informed of the nature of the above surgery/procedure, the discomforts, risks and benefits associated with it.

Signed: _____ Date: _____
(Patient's Signature)

Witness: _____ Date: _____
(Print name of Witness)

Signed: _____ Date: _____
(Witness Signature)

SECTION	Approval date:	
Personnel	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Informed Consent	Revision date:	

POLICY:

Site personnel receive training and/or information on member rights that include informed consent, human sterilization consent.

PROCEDURE:

I. Written Member Rights should be available at the office site. Staff should be able to locate the written Member Rights list and explain how to use the information.

II. Staff trainings regarding member rights may be part of office staff education documented in:
- Informal or formal in-services
- New staff orientation
- External training courses

III. Informed Consent

Patients shall be informed about any proposed treatment or procedure that includes medically significant risks, alternate courses of treatment or non-treatment and the risks involved in each and the name of the person who will carry out the procedure or treatment. Documentation of this discussion and the signed consent shall be written and included in the member's medical record.

Note: Patient rights incorporate the requirements of the Joint Commission, Title 22, California Code of Regulations, Section 70707 and Medicare Conditions of Participation.

Requirements include but are not limited to:
- Conducted by physician or physician designee
- Offered booklet published by the DHCS and copy of consent form must be given to the member
- Provided answers to any question the member may have
- Inform the member they may withdraw or withhold consent to procedure at any time before the sterilization
- Describe fully the available alternatives of family planning and birth control
- Advise that the sterilization procedure is considered irreversible
- Explain fully the description of discomforts and risks and benefits of the procedure
- Utilize the PM330 human sterilization consent form. Forms may be ordered directly from the DHCS by placing a request to:

Department of Health Care Services Warehouse
1037 North Market Blvd., Suite 9
Sacramento, CA 95834
Fax: 916-928-1328

NOTE: Department of Health Care Services COB Letter 87-1 revision 2 and Title 22 code or regulations Sections 51163 and 501305.1-513-5.7 define Medi-Cal Sterilization and Hysterectomy Regulations and Procedures.

Sensitive Services

"Sensitive services" means those services that are defined as services related to sexual assault, substance or alcohol abuse, pregnancy, family planning, and sexually transmitted diseases for members 12 years of age and older.

Members 12 years of age and older may sign an Authorization for Treatment form for any sensitive services [without parental consent]. Parental or guardian consent is required for members under 12 years of age who seek substance or alcohol abuse treatment services, or for treatment of sexually transmitted diseases.

The member's PCP should encourage members to use in-plan services to enhance coordination of care. However, members may access sensitive services [through out-of-network] without prior authorization.

"Family Planning [Sensitive] Services shall include, but not be limited to:

- Medical treatment and procedures defined as family planning services under current Medi-Cal scope of benefits.
- Medical contraceptive services including diagnosis, treatment, supplies, and follow-up.
- Informational and education services.

In compliance with Federal regulations, members have free access to confidential family planning services from any family planning provider or agency without obtaining prior authorization for these services. Access to sensitive services will be timely. Services to treat sexually transmitted diseases or referrals to substance and alcohol treatment are confidential.

<u>EXAMPLES OF COVERED SERVICES</u>:

1. Routine pregnancy testing
2. Elective therapeutic abortions
3. Birth control pills
4. "Morning after pill" to avoid pregnancy is approved by the FDA for emergency treatment only. Examples of emergency are rape and incest.
5. Depo-provera as routine birth control
6. Norplant, including device, insertion and removal
7. Intra-uterine device (IUD) including device, insertion and removal
8. Diaphragm
9. Contraceptive foam, male and female condoms, cervical caps, sponges, etc.
10. Elective tubal ligation
11. Elective vasectomy
12. Office visits for education and instruction for birth control, including Symptom-Thermal method, billings procedure, and rhythm method, and instruction and education regarding the methods and devices listed above.
13. STD screening, testing, diagnosis, education, and referrals for treatment
14. HIV screening, testing, diagnosis, education and referrals for treatment

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Minor's Rights and Sensitive Services	Revision date:	

POLICY:

Site personnel receive training and/or information on member rights that include minors' rights to sensitive services.

PROCEDURE:

I. Written Member Rights shall be available at the office site. Staff shall be able to locate the written Member Rights list and explain how to use the information.

II. Staff trainings regarding member rights shall be part of office staff education documented in:
- Informal or formal in-services
- New staff orientation
- External training courses

III. Minors' Rights and Sensitive Services

A. A minor may consent to the minors' medical care or dental care if all of the following conditions are satisfied:
1. The minor is 15 years of age or older
2. The minor is living separately and apart from the minor's parents or guardian whether with or without the consent of a parent or guardian and regardless of the duration of the separate residence
3. The minor is managing the minor's own financial affairs, regardless of the source of the minor's income

B. A physician, surgeon, or dentist may, with or without the consent of the minor patient, advise the minor's parent or guardian of the treatment given or needed if the physician and surgeon or dentist has reason to know, on the basis of the information given by the minor, the whereabouts of the parent or guardian.

C. A minor who is 12 years of age or older and who may have come into contact with an infectious, contagious, or communicable disease may consent to medical care related to the diagnosis or treatment of the disease, if the disease or condition is one that is required by law or regulation adopted pursuant to law to be reported to the local health officer, or is a related sexually transmitted disease, as may be determined by the State Public Health Officer. A minor who is 12 years of age or older may consent to medical care related to the prevention of a sexually transmitted disease.

D. A minor who is 12 years of age or older and who is alleged to have been raped may consent to medical care related to the diagnosis or treatment of the condition and the collection of medical evidence with regard to the alleged rape.

E. A minor who is alleged to have been sexually assaulted may consent to medical care related to the diagnosis and treatment of the condition, and the collection of medical evidence with regard to the alleged sexual assault. The professional person providing medical treatment shall attempt to contact the minor's parent or guardian and shall note in the minor's treatment record the date and time the professional person attempted to contact the parent or guardian and whether the attempt was successful or unsuccessful. This does not apply if the professional person reasonably believes that the minor's parent or guardian committed the sexual assault on the minor.

F. A minor who is 12 years of age or older may consent to medical care and counseling relating to the diagnosis and treatment of a drug- or alcohol-related problem.

G. A minor who is 12 years of age or older and who states that the minor is injured as a result of intimate partner violence may consent to medical care related to the diagnosis or treatment of the injury and the collection of medical evidence with regard to the alleged intimate partner violence.

H. Special precautions must be taken to ensure that communications (written, verbal or electronic communications) regarding the medical information of a minor related to sensitive services is protected and shall NOT be directed to the home without the minor's authorization.

1. Comminications are directly to minor's designated alternative mailing address, email address, or telephone number; OR,
2. In the absence of a designated alternative mailing address, email address, or telephone number: to the address or telephone number on file in the name of the minor.
3. Communications regarding a protected minor's receipt of sensitive services shall include:
   - Bills and attempts to collect payment.
   - A notice of adverse benefits determinations.
   - An explanation of benefits notice.
   - A plan's request for additional information regarding a claim.
   - A notice of a contested claim.
   - The name and address of a provider, description of services provided, and other information related to a visit.
   - Any written, oral, or electronic communication from a plan that contains protected health information.

I. The minors' parents or guardian are not liable for payment for medical care provided pursuant to this section.

RESOURCES: California Law Family Code Section 6920-6930
Civil Code Section 56 et seq.

ATTACHMENT: California Minor Consent and Confidentiality Laws

REFERRAL PROCEDURES

Definitions: Referrals are required when the primary care physician (PCP) cannot provide medically necessary services.

Purpose: To assure that access to medical care services is provided appropriately to members in a manner that ensures continuity of care through the most efficient use of benefit coverage and resources.

Procedure: The primary care physician serves as the medical case manager. He/She is responsible for making referrals and coordinating medically necessary services required by the member, both inside and outside the provider network.

Ancillary, X-Rays, Specialty Physician Consults

The PCP will complete the following:

1. Discuss the need for referral/consult with the member.
2. Authorize the referral or obtain authorization from the plan provider Utilization Management Committee/Department*, when required.
3. Refer the member to the appropriate specialist or facility. (*The PCP, office staff or member may arrange the referral appointment.)*
4. Document the referral in the member's medical record, and attach any authorization paperwork.
5. Send all documents pertaining to the diagnosis (lab results, x-rays, last progress notes, etc.) with the referral. Discuss the case, as necessary, with the referral provider.
6. Receive reports and feedback from the referral provider regarding the consultation and treatment. (*The referral provider or the referral facility must send a written report to the PCP within five (5) working days of the visit.)*
7. Discuss the results of the referral and any plan for further treatment, if needed, and coordination of that care with the member.
8. Referral will be tracked by the PCP's office for follow-up through a log or computerized tracking process. The log or tracking mechanism should include, but not be limited to, the following:

    - Date of referral or request for authorization
    - Patient Name and Identification Number (Example: DOB, Medical Record #, Social Security #)
    - Name of Appropriate Specialist or Facility
    - Reason/Diagnosis
    - Date of Authorization Approval/Denial/or Deferral
    - Date of Appointment
    - Date of Report Received
    - PCP office will follow up with members on all referrals that have not been used

9. The specialist/laboratory must perform only those services/tests/procedures, which have been authorized.

    - All additional tests, procedures, treatments, etc., must have prior authorization. Services performed without authorization may not be reimbursed to the service provider.
    - The specialist will not seek reimbursement from the patient for services referred and performed, but not authorized.

Hospital Admissions/Procedures

1. Hospital inpatient care may be pre-planned and pre-authorized, or may be urgent.
2. The PCP is responsible for obtaining required pre-authorizations for inpatient care from the plan provider.
3. The PCP must notify the plan provider of an emergency admission the next business day.
4. While the member is hospitalized, the PCP must coordinate care as contained in the policies and procedures of the plan provider.

*Refer to the Plan Provider Manual for listing of services requiring prior authorization.

Signature of Provider

Signature of Referral Staff

Referral Tracking Log

Dr.:_____ **Month:** _____

Referral Date	Member Name	Health Plan	Type of Referral*	Reason for Referral/DX	Service Requested	Date Rec'd from UR	Status of Referral**	Date Patient Notified	Date Appt. Scheduled	Date Consult Report Rec'd	Date of Follow Up if Report not Received

* Type of Referral: Urgent, Emergent, or Routine

** Status of Referral: Approved, Modified, Deferred, Denied

SAMPLE ONLY

Referral Tracking Log

Dr.: John Smith, MD **Month:** April 2013

Referral Date	Member Name	Health Plan	Type of Referral*	Reason for Referral/DX	Service Requested	Date Rec'd from UR	Status of Referral**	Date Patient Notified	Date Appt. Scheduled	Date Consult Report Rec'd	Date of Follow Up if Report not Received
4/1/13	Jane Doe	ABC	Routine	Pap Smear	OB/GYN	4/3/13	Approved	4/3/13	4/8/13	4/12/13	
4/3/13	John Doe	ABC	Routine	Stress Test	Cardiology	4/5/13	Approved	4/5/13	4/10/13		5/14/13
	A system must be in place to track receipt of consult reports										

* Type of Referral: Urgent, Emergent, or Routine

** Status of Referral: Approved, Modified, Deferred, Denied

SECTION	Approval date:	
Office Management	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Referrals Process / Prior Authorizations	**Revision date:**	

POLICY:

Referrals for specialty care and medical procedures shall be processed in a timely manner.

PROCEDURE:

I. REFERRAL FORMS

A. Appropriate referral forms shall be available at the primary care physician site. The practitioner shall complete the referral form and attach all relevant medical information to obtain prior authorization from the entity responsible for payment as necessary. Refer to the Health Plan specific referral forms.

B. Primary care Physician offices are required to maintain a “Referral Tracking Log” or an appropriate tickler system. Refer to the referral tracking log attached.

C. The following elements should be included within the referral system:
- Patient Name
- Date of Referral
- Referral Type
- Authorization Status
- Appointment Date
- Appointment Kept or Failed
- Date Report Received
- Physician Follow-up/Documentation

D. The PCP must ensure timely receipt of the specialist’s report or medical procedure report. Reports must be filed in the patient’s medical record within 30 days of the scheduled procedure or appointment. If the PCP site has not received the report within 30 days, the PCP should contact the specialist/procedure site to request a copy of the report.

E. Site staff shall be able to demonstrate (e.g., “walk-through”) the office referral process from beginning to end.

Member Grievance Policy and Procedure

Definition per CMS.gov: Any complaint or dispute, other than an organization determination, expressing dissatisfaction with the manner in which a Medicare health plan or delegated entity provides health care services, regardless of whether any remedial action can be taken.

An expedited grievance may also include a complaint that a Medicare health plan refused to expedite an organization determination or reconsideration, or invoked an extension to an organization determination or reconsideration time frame.

In addition, grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided health service, procedure, or item. Grievance issues may also include complaints that a covered health service procedure or item during a course of treatment did not meet accepted standards for delivery of health care.

Purpose: To assure the quality and continuity of care given to patient/members. To monitor and resolve all quality of care issues and administrative issues through an internal grievance process.

Grievance procedure: at initial enrollment, upon involuntary disenrollment initiated by the Medicare health plan, upon denial of an enrollee's request for expedited review of an organization determination or appeal, upon an enrollee's request, and annually thereafter;

Procedure to file a grievance:

1. An enrollee or their representative may make the complaint or dispute, either orally or in writing, to a Medicare health plan, provider, or facility.
2. Grievances may be filed by enrollee or their representative either orally or in writing no later than 60 days after the triggering event or incident precipitating the grievance.
3. Whether grievance is filed in person, telephonic or by correspondence, the office personnel must document the grievance on a grievance report form and submit a copy to the member's Health Plan.
4. Grievance form must be completed in its entirety with as much detail as possible.
5. If grievance is solvable by the physician and/or office personnel, the documentation of the grievance must be kept on file and recorded on the grievance log and copy submitted to member's Health Plan.
6. If grievance is no solvable by the physician and/or office personnel, then a copy of the grievance form and any supporting documents must be sent to the member's Medical Group/IPA. Member must be offered the opportunity to file a grievance with their Health Plan.

NOTE: All grievance forms, grievance logs and supporting documents must be kept in a separate folder, not in the patient's medical records.

GRIEVANCE REPORT FORM

Date: _____

Patient Name: _____ **Date of Birth:** _____

Grievance filed by (Check those that apply:

_____ Administration _____ Back office staff _____ Front office staff
_____ Laboratory _____ Medical Assistant (MA) _____ Medical Records
_____ Nursing Staff (RN/LVN) _____ Physician/Physician Assistant(MD/PA)_____ X-Ray

Employee involved:

1. _____ (Name/Title/Department)
2. _____ (Name/Title/Department)
3. _____ (Name/Title/Department)
4. _____ (Name/Title/Department)
5. _____ (Name/Title/Department)

Reason for grievance/complaint:

_____

_____

_____

_____

_____

Investigative report:

_____

_____

_____

_____

_____

Action take: _____ Referred to physician: _____ Referred to HealthPlan/IPA: _____ Other: _____

Resolution:

_____

_____

Any supporting documents submitted? _____ Yes ____ No

If no, attach original documents(s) to the grievance form.

_____ _____

Patient signature and date Office staff signature and date

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Member Grievances/Complaints	Revision date:	

POLICY:

The site has an established process for member grievances and complaints.

DEFINITION:

A “grievance” is defined as any written or oral expression of dissatisfaction that involves coverage dispute, healthcare medical necessity, experimental or investigational treatment. The health plan does not delegate the resolution of grievances to contracted medical groups.

A “complaint” is any expression of dissatisfaction regarding the quality of service (excluding quality of care) which can be resolved in the initial contact. A “complaint” is self-limiting (e.g., service complaints, appointment wait times) that can be resolved to the member’s satisfaction, such as they do not ask for additional assistance

PROCEDURE:

A. The staff shall ensure that any member who expresses a grievance or complaint is informed of the right for a State Fair Hearing and offered the following numbers:

- The California Department of managed health Care: 1-888-HMO-2219
- For Hearing and Speech impaired persons call: 1-800-735-2929
- State Fair Hearing: 1-800-952-5253

B. Staff shall ensure that grievance forms (in threshold languages) for each participating health plan shall be provided to members promptly upon request.
    - The grievance form must be submitted to the health plan within one (1) business day

C. The staff shall ensure that all complaints (e.g., service complaints, appointment wait times) are tracked and submitted to the health plan after each occurrence.

- These complaints may be resolved at the point of service
- Log the complaint to include the following information:
    a. Date of complaint
    b. Name of complainant and ID#
    c. Nature of the complaint
    d. Resolution/action taken (include information communicated to health plan, as appropriate)
    e. Date of resolution/action
    f. Date log submitted to health plan

ADULT/CHILD ABUSE & DOMESTIC VIOLENCE REPORTING

Reporting Requirements:
California law requires that medical practitioners, health practitioners and child care custodians working in specified public or private facilities be informed of their duty to report suspected child abuse, suspected dependent adult abuse, and suspected domestic violence.

Who Must Report:
The following individuals are legally mandated reporters:
(Refer to "Reporting Law" Section for a comprehensive listing).

- Child visitation monitors
- Health practitioners (nurses, physicians, etc.)

  § 15610.37 "Health Practitioner" means a physician and surgeon, psychiatrist, psychologist, dentist, resident, intern, podiatrist, chiropractor, licensed nurse, dental hygienist, licensed clinical social worker or associate clinical social worker, marriage, family and child counselor, or any other person who is currently licensed under Division 2 (commencing with Section 500) of the Business and Professions Code, any emergency medical technician I or II, paramedic or person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code, a psychological assistant registered pursuant to Section 2913 of Business and Professions Code, a marriage, family, and child counselor trainee, as defined in subdivision (c) of Section 4980.03 of the Business and Professions Code, or an unlicensed marriage, family, and child counselor intern registered under Section 4980.44 of the Business and Professions Code, state or county public health or social services employee who treats an elder or a dependent adult for any condition, or a coroner.
- Commercial or photographic print processors in specified instances
- Specified public positions (teachers, social workers, probation officers, etc.)
- Public protection positions (police, sheriff, CPS, etc.)
- Clergy members
- Fire fighters (except volunteer firefighters), Animal control officers, Humane society office

To Whom Do You Report?
The report must be made to a county welfare department or probation department (if designated by the county to receive mandated reports) or a police or sheriff's department, not including a school district police or security department. (P.C. 11165.9)
Reports by commercial print and photographic print processors are to be made to the law enforcement agency having jurisdiction immediately or as soon as practically possible. (P.C.11166(d)).

Source:
Department of Social Services Website:
http://www.dss.cahwnet.gov/cdssweb/default.htm
California home page: http://www.ca.gov

HEALTH AND SAFETY CODE SECTION 1225-1234

1233.5. By June 30, 1995, a licensed clinic board of directors and its medical director shall establish and adopt written policies and procedures to screen patients for purposes of detecting spousal or partner abuse. The policies shall include procedures to accomplish all of the following:

(a) Identifying, as part of its medical screening, spousal or partner abuse among patients.

(b) Documenting in the medical record patient injuries or illnesses attributable to spousal or partner abuse.

(c) Providing to patients who exhibit signs of spousal or partner abuse a current referral list of private and public community agencies that provide, or arrange for, the evaluation, counseling, and care of persons experiencing spousal or partner abuse, including, but not limited to, hot lines, local battered women's shelters, legal services, and information about temporary restraining orders.

(d) Designating licensed clinical staff to be responsible for the implementation of these guidelines.

It is the intent of the Legislature that clinics, for purposes of satisfying the requirements of this section, adopt guidelines similar to those developed by the American Medical Association regarding domestic violence detection and referral. The Legislature recognizes that while guidelines evolve and change, the American Medical Association's guidelines may serve, at this time, as a model for clinics to follow.

Source:
http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=01001-02000&file=1225-1234

California Mandated Reporter Penal Code 11165.9.

11165.9. Reports of suspected child abuse or neglect shall be made by mandated reporters, or in the case of reports pursuant to Section 11166.05, may be made, to any police department or sheriff's department, not including a school district police or security department, county probation department, if designated by the county to receive mandated reports, or the county welfare department. Any of those agencies shall accept a report of suspected child abuse or neglect whether offered by a mandated reporter or another person, or referred by another agency, even if the agency to whom the report is being made lacks subject matter or geographical jurisdiction to investigate the reported case, unless the agency can immediately electronically transfer the call to an agency with proper jurisdiction. When an agency takes a report about a case of suspected child abuse or neglect in which that agency lacks jurisdiction, the agency shall immediately refer the case by telephone, fax, or electronic transmission to an agency with proper jurisdiction. Agencies that are required to receive reports of suspected child abuse or neglect may not refuse to accept a report of suspected child abuse or neglect from a mandated reporter or another person unless otherwise authorized pursuant to this section, and shall maintain a record of all reports received.

Source:
http://www.leginfo.ca.gov/cgi-bin/displaycode?section=pen&group=11001-12000&file=11164-11174.3

California Mandated Reporter Penal Code 11165.7.

11165.7. (a) As used in this article, "mandated reporter" is defined as any of the following:
(1) A teacher.
(2) An instructional aide.
(3) A teacher's aide or teacher's assistant employed by any public or private school.
(4) A classified employee of any public school.
(5) An administrative officer or supervisor of child welfare and attendance, or a certificated pupil personnel employee of any public or private school.
(6) An administrator of a public or private day camp.
(7) An administrator or employee of a public or private youth center, youth recreation program, or youth organization.
(8) An administrator or employee of a public or private organization whose duties require direct contact and supervision of children.
(9) Any employee of a county office of education or the State Department of Education, whose duties bring the employee into contact with children on a regular basis.
(10) A licensee, an administrator, or an employee of a licensed community care or child day care facility.
(11) A Head Start program teacher.
(12) A licensing worker or licensing evaluator employed by a licensing agency as defined in Section 11165.11.
(13) A public assistance worker.
(14) An employee of a child care institution, including, but not limited to, foster parents, group home personnel, and personnel of residential care facilities.
(15) A social worker, probation officer, or parole officer.
(16) An employee of a school district police or security department.
(17) Any person who is an administrator or presenter of, or a counselor in, a child abuse prevention program in any public or private school.
(18) A district attorney investigator, inspector, or local child support agency caseworker unless the investigator, inspector, or caseworker is working with an attorney appointed pursuant to Section 317 of the Welfare and Institutions Code to represent a minor.
(19) A peace officer, as defined in Chapter 4.5 (commencing with Section 830) of Title 3 of Part 2, who is not otherwise described in this section.
(20) A firefighter, except for volunteer firefighters.
(21) A physician and surgeon, psychiatrist, psychologist, dentist, resident, intern, podiatrist, chiropractor, licensed nurse, dental hygienist, optometrist, marriage and family therapist, clinical social worker, professional clinical counselor, or any other person who is currently licensed under Division 2 (commencing with Section 500) of the Business and Professions Code.
(22) Any emergency medical technician I or II, paramedic, or other person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code.
(23) A psychological assistant registered pursuant to Section 2913 of the Business and Professions Code.
(24) A marriage and family therapist trainee, as defined in subdivision (c) of Section 4980.03 of the Business and Professions Code.
(25) An unlicensed marriage and family therapist intern registered under Section 4980.44 of the Business and Professions Code.
(26) A state or county public health employee who treats a minor for venereal disease or any other condition.
(27) A coroner.
(28) A medical examiner, or any other person who performs autopsies.
(29) A commercial film and photographic print processor, as specified in subdivision (e) of Section 11166. As used in this article, "commercial film and photographic print processor" means any person who develops exposed photographic film into negatives, slides, or prints, or who makes prints from negatives or slides, for compensation. The term includes any employee of such a person; it does not include a person who develops film or makes prints for a public agency.
(30) A child visitation monitor. As used in this article, "child visitation monitor" means any person who, for financial compensation, acts as monitor of a visit between a child and any other person when the monitoring of that visit has been ordered by a court of law.
(31) An animal control officer or humane society officer. For the purposes of this article, the following terms have the following meanings:
(A) "Animal control officer" means any person employed by a city, county, or city and county for the purpose of enforcing animal control laws or regulations.
(B) "Humane society officer" means any person appointed or employed by a public or private entity as a humane officer who is qualified pursuant to Section 14502 or 14503 of the Corporations Code.
(32) A clergy member, as specified in subdivision (d) of Section 11166. As used in this article, "clergy member" means a priest, minister, rabbi, religious practitioner, or similar functionary of a church, temple, or recognized denomination or organization.
(33) Any custodian of records of a clergy member, as specified in this section and subdivision (d) of Section 11166.
(34) Any employee of any police department, county sheriff's department, county probation department, or county welfare department.
(35) An employee or volunteer of a Court Appointed Special Advocate program, as defined in Rule 1424 of the California Rules of Court.
(36) A custodial officer as defined in Section 831.5.
(37) Any person providing services to a minor child under Section 12300 or 12300.1 of the Welfare and Institutions Code.
(38) An alcohol and drug counselor. As used in this article, an "alcohol and drug counselor" is a person providing counseling, therapy, or other clinical services for a state licensed or certified drug, alcohol, or drug

and alcohol treatment program. However, alcohol or drug abuse, or both alcohol and drug abuse, is not in and of itself a sufficient basis for reporting child abuse or neglect.

(39) A clinical counselor trainee, as defined in subdivision (g) of Section 4999.12 of the Business and Professions Code.

(40) A clinical counselor intern registered under Section 4999.42 of the Business and Professions Code.

(b) Except as provided in paragraph (35) of subdivision (a) volunteers of public or private organizations whose duties require direct contact with and supervision of children are not mandated reporters but are encouraged to obtain training in the identification and reporting of child abuse and neglect and are further encouraged to report known or suspected instances of child abuse or neglect to an agency specified in Section 11165.9.

(c) Employers are strongly encouraged to provide their employees who are mandated reporters with training in the duties imposed by this article. This training shall include training in child abuse and neglect identification and training in child abuse and neglect reporting. Whether or not employers provide their employees with training in child abuse and neglect identification and reporting, the employers shall provide their employees who are mandated reporters with the statement required pursuant to subdivision (a) of Section 11166.5.

(d) School districts that do not train their employees specified in subdivision (a) in the duties of mandated reporters under the child abuse reporting laws shall report to the State Department of Education the reasons why this training is not provided.

(e) Unless otherwise specifically provided, the absence of training shall not excuse a mandated reporter from the duties imposed by this article.

(f) Public and private organizations are encouraged to provide their volunteers whose duties require direct contact with and supervision of children with training in the identification and reporting of child abuse and neglect.

Source:
http://www.leginfo.ca.gov/cgi-bin/displaycode?section=pen&group=11001-12000&file=11164-11174.3

STATE OF CALIFORNIA – HEALTH AND HUMAN SERVICES AGENCY

CALIFORNIA DEPARTMENT OF SOCIAL SERVICES

CONFIDENTIAL REPORT - NOT SUBJECT TO PUBLIC DISCLOSURE

REPORT OF SUSPECTED DEPENDENT ADULT/ELDER ABUSE

DATE COMPLETED:

TO BE COMPLETED BY REPORTING PARTY. PLEASE PRINT OR TYPE. SEE GENERAL INSTRUCTIONS.

A. VICTIM ☐ Check box if victim consents to disclosure of information [Ombudsman use only - WIC 15636(a)]

*NAME (LAST NAME FIRST)	*AGE	DATE OF BIRTH	SSN	GENDER ☐ M ☐ F	ETHNICITY	LANGUAGE (✔ CHECK ONE) ☐ NON-VERBAL ☐ ENGLISH ☐ OTHER (*SPECIFY*)

*ADDRESS (IF FACILITY, INCLUDE NAME AND NOTIFY OMBUDSMAN)	*CITY	*ZIP CODE	*TELEPHONE
			( )
*PRESENT LOCATION (IF DIFFERENT FROM ABOVE)	*CITY	*ZIP CODE	*TELEPHONE
			( )

☐ ELDERLY (65+) ☐ DEVELOPMENTALLY DISABLED ☐ MENTALLY ILL/DISABLED ☐ PHYSICALLY DISABLED ☐ UNKNOWN/OTHER ☐ LIVES ALONE ☐ LIVES WITH OTHERS

B. SUSPECTED ABUSER ✔ Check if ☐ Self-Neglect

NAME OF SUSPECTED ABUSER

☐ CARE CUSTODIAN (type)_____ ☐ PARENT ☐ SON/DAUGHTER ☐ OTHER_____

☐ HEALTH PRACTITIONER (type)_____ ☐ SPOUSE ☐ OTHER RELATION_____

ADDRESS	*ZIP CODE	TELEPHONE	GENDER	ETHNICITY	AGE	D.O.B.	HEIGHT	WEIGHT	EYES	HAIR
		( )	☐ M ☐ F							

C. REPORTING PARTY: *Check appropriate box if reporting party waives confidentiality to:* ☐ ✔ All ☐ ✔ All but victim ☐ ✔ All but perpetrator

*NAME (PRINT)	SIGNATURE	OCCUPATION	AGENCY/NAME OF BUSINESS

RELATION TO VICTIM/HOW KNOWS OF ABUSE	(STREET)	(CITY)	(ZIP CODE)	(E-MAIL ADDRESS)	TELEPHONE
					( )

D. INCIDENT INFORMATION - Address where incident occurred:

*DATE/TIME OF INCIDENT(S)

PLACE OF INCIDENT (✔ CHECK ONE)

☐ OWN HOME ☐ COMMUNITY CARE FACILITY ☐ HOSPITAL/ACUTE CARE HOSPITAL

☐ HOME OF ANOTHER ☐ NURSING FACILITY/SWING BED ☐ OTHER (Specify)

E. REPORTED TYPES OF ABUSE (✔ CHECK ALL THAT APPLY).

1. PERPETRATED BY OTHERS (WIC 15610.07 & 15610.63)

a. PHYSICAL
- ☐ ASSAULT/BATTERY
- ☐ CONSTRAINT OR DEPRIVATION
- ☐ SEXUAL ASSAULT
- ☐ CHEMICAL RESTRAINT
- ☐ OVER OR UNDER MEDICATION

b. ☐ NEGLECT
c. ☐ FINANCIAL
d. ☐ ABANDONMENT
e. ☐ ISOLATION
f. ☐ ABDUCTION
g. ☐ OTHER (Non-Mandated: e.g., deprivation of goods and services: psychological/mental)

2. SELF-NEGLECT (WIC 15610.57(b)(5))

a. ☐ PHYSICAL CARE (e.g., personal hygiene, food, clothing, shelter)
b. ☐ MEDICAL CARE (e.g., physical and mental health needs)
c. ☐ HEALTH and SAFETY HAZARDS
d. ☐ MALNUTRITION/DEHYDRATION
e. ☐ OTHER (Non-Mandated e.g., financial)

ABUSE RESULTED IN (✔ CHECK ALL THAT APPLY) ☐ NO PHYSICAL INJURY ☐ MINOR MEDICAL CARE ☐ HOSPITALIZATION ☐ CARE PROVIDER REQUIRED ☐ DEATH ☐ MENTAL SUFFERING ☐ OTHER (SPECIFY) ☐ UNKNOWN

F. REPORTER'S OBSERVATIONS, BELIEFS, AND STATEMENTS BY VICTIM IF AVAILABLE. DOES ALLEGED PERPETRATOR STILL HAVE ACCESS TO THE VICTIM? PROVIDE ANY KNOWN TIME FRAME (2 days, 1 week, ongoing, etc.). *LIST ANY POTENTIAL DANGER FOR INVESTIGATOR (animals, weapons, communicable diseases, etc.).* ☐ ✔CHECK IF MEDICAL, FINANCIAL, PHOTOGRAPHS OR OTHER SUPPLEMENTAL INFORMATION IS ATTACHED.

G. TARGETED ACCOUNT

ACCOUNT NUMBER (LAST 4 DIGITS):	TYPE OF ACCOUNT: ☐ DEPOSIT ☐ CREDIT ☐ OTHER	TRUST ACCOUNT: ☐ YES ☐ NO
POWER OF ATTORNEY: ☐ YES ☐ NO	DIRECT DEPOSIT: ☐ YES ☐ NO	OTHER ACCOUNTS: ☐ YES ☐ NO

H. OTHER PERSON BELIEVED TO HAVE KNOWLEDGE OF ABUSE. *(family, significant others, neighbors, medical providers and agencies involved, etc.)*

NAME	ADDRESS	TELEPHONE NO.	RELATIONSHIP
		( )	

I. FAMILY MEMBER OR OTHER PERSON RESPONSIBLE FOR VICTIM'S CARE. *(If unknown, list contact person).*

*NAME	IF CONTACT PERSON ONLY ✔ CHECK ☐	*RELATIONSHIP

*ADDRESS	*CITY	*ZIP CODE	*TELEPHONE
			( )

J. TELEPHONE REPORT MADE TO: ☐ Local APS ☐ Local Law Enforcement ☐ Local Ombudsman ☐ Calif. Dept. of Mental Health ☐ Calif. Dept. of Developmental Services

NAME OF OFFICIAL CONTACTED BY PHONE	*TELEPHONE	DATE/TIME
	( )	

K. WRITTEN REPORT Enter information about the agency receiving this report. Do not submit report to California Department of Social Services Adult Programs Bureau.

AGENCY NAME	ADDRESS OR FAX #	☐ Date Mailed: ☐ Date Faxed:

L. RECEIVING AGENCY USE ONLY ☐ Telephone Report ☐ Written Report

1. Report Received by: Date/Time:

2. Assigned ☐ Immediate Response ☐ Ten-day Response ☐ No Initial Face-To-Face Required ☐ Not APS ☐ Not Ombudsman

Approved by: Assigned to (optional):

3. Cross-Reported to: ☐ CDHS, Licensing & Cert.; ☐ CDSS-CCL; ☐ CDA Ombudsman; ☐ Bureau of Medi-Cal Fraud & Elder Abuse; ☐ Mental Health; ☐ Law Enforcement; ☐ Professional Board; ☐ Developmental Services; ☐ APS; ☐ Other (Specify) Date of Cross-Report:

4. APS/Ombudsman/Law Enforcement Case File Number:_____

REPORT OF SUSPECTED DEPENDENT ADULT/ELDER ABUSE
GENERAL INSTRUCTIONS

PURPOSE OF FORM

This form, as adopted by the California Department of Social Services (CDSS), is required under Welfare and Institutions Code (WIC) Sections 15630 and 15658(a)(1). This form documents the information given by the reporting party on the suspected incident of abuse of an elder or dependent adult. "**Elder**," means any person residing in this state who is 65 years of age or older (WIC Section 15610.27). **"Dependent Adult,"** means any person residing in this state, between the ages of 18 and 64, who has physical or mental limitations that restrict his or her ability to carry out normal activities or to protect his or her rights including, but not limited to, persons who have physical or developmental disabilities or whose physical or mental abilities have diminished because of age (WIC Section 15610.23). Dependent adult includes any person between the ages of 18 and 64 who is admitted as an inpatient to a 24-hour health facility (defined in the Health and Safety Code Sections 1250, 1250.2, and 1250.3).

COMPLETION OF THE FORM

1. This form may be used by the receiving agency to record information through a telephone report of suspected dependent adult/elder abuse. Complete items with an asterisk (*) when a telephone report of suspected abuse is received as required by statute and the California Department of Social Services.
2. If any item of information is unknown, enter "unknown."
3. Item A: Check box to indicate if the victim waives confidentiality.
4. Item C: Check box if the reporting party waives confidentiality. Please note that mandated reporters are required to disclose their names, however, non-mandated reporters may report anonymously.

REPORTING RESPONSIBILITIES

Mandated reporters (see definition below under "Reporting Party Definitions") shall complete this form for each report of a known or suspected instance of abuse (physical abuse, sexual abuse, financial abuse, abduction, neglect, (self-neglect), isolation, and abandonment (see definitions in WIC Section 15610) involving an elder or a dependent adult. **The original of this report shall be submitted within two (2) working days of making the telephone report to the responsible agency as identified below:**

- The county Adult Protective Services (APS) agency or the local law enforcement agency (if abuse occurred in a private residence, apartment, hotel or motel, or homeless shelter).
- Long-Term Care Ombudsman (LTCO) program or the local law enforcement agency (if abuse occurred in a nursing home, adult residential facility, adult day program, residential care facility for the elderly, or adult day health care center).
- The California Department of Mental Health or the local law enforcement agency (if abuse occurred in Metropolitan State Hospital, Atascadero State Hospital, Napa State Hospital, or Patton State Hospital).
- The California Department of Developmental Services or the local law enforcement agency (if abuse occurred in Sonoma Developmental Center, Lanterman Developmental Center, Porterville Developmental Center, Fairview Developmental Center, or Agnews Developmental Center).

WHAT TO REPORT

Any mandated reporter who, in his or her professional capacity, or within the scope of his or her employment has observed, suspects, or has knowledge of an incident that reasonably appears to be physical abuse (including sexual abuse), abandonment, isolation, financial abuse, abduction, or neglect (including self-neglect), or is told by an elder or a dependent adult that he or she has experienced behavior constituting physical abuse, abandonment, isolation, financial abuse, abduction, or neglect, shall report the known or suspected instance of abuse by telephone immediately or as soon as practicably possible, and by written report sent within two working days to the appropriate agency.

REPORTING PARTY DEFINITIONS

Mandated Reporters (WIC) "15630 (a) Any person who has assumed full or intermittent responsibility for care or custody of an elder or dependent adult, whether or not that person receives compensation, including administrators, supervisors, and any licensed staff of a public or private facility that provides care or services for elder or dependent adults, or any elder or dependent adult care custodian, health practitioner, clergy member, or employee of a county adult protective services agency or a local law enforcement agency, is a mandated reporter."

Care Custodian (WIC) "15610.17 'Care custodian' means an administrator or an employee of any of the following public or private facilities or agencies, or persons providing care or services for elders or dependent adults, including members of the support staff and maintenance staff: (a) Twenty-four-hour health facilities, as defined in Sections 1250, 1250.2, and 1250.3 of the Health and Safety Code. (b) Clinics. (c) Home health agencies. (d) Agencies providing publicly funded in-home supportive services, nutrition services, or other home and community-based support services. (e) Adult day health care centers and adult day care. (f) Secondary schools that serve 18- to 22-year-old dependent adults and postsecondary educational institutions that serve dependent adults or elders. (g) Independent living centers. (h) Camps. (i) Alzheimer's Disease Day Care Resource Centers. (j) Community care facilities, as defined in Section 1502 of the Health and Safety Code, and residential care facilities for the elderly, as defined in Section 1569.2 of the Health and Safety Code. (k) Respite care facilities. (l) Foster homes. (m) Vocational rehabilitation facilities and work activity centers. (n) Designated area agencies on aging. (o) Regional centers for persons with developmental disabilities. (p) State Department of Social Services and State Department of Health Services licensing divisions. (q) County welfare departments. (r) Offices of patients' rights advocates and clients' rights advocates, including attorneys. (s) The Office of the State Long-Term Care Ombudsman. (t) Offices of public conservators, public guardians, and court investigators. (u) Any protection or advocacy

GENERAL INSTRUCTIONS (Continued)

agency or entity that is designated by the Governor to fulfill the requirements and assurances of the following: (1) The federal Developmental Disabilities Assistance and Bill of Rights Act of 2000, contained in Chapter 144 (commencing with Section 15001) of Title 42 of the United States Code, for protection and advocacy of the rights of persons with developmental disabilities. (2) The Protection and Advocacy for the Mentally Ill Individuals Act of 1986, as amended, contained in Chapter 114 (commencing with Section 10801) of Title 42 of the United States Code, for the protection and advocacy of the rights of persons with mental illness. (v) Humane societies and animal control agencies. (w) Fire departments. (x) Offices of environmental health and building code enforcement. (y) Any other protective, public, sectarian, mental health, or private assistance or advocacy agency or person providing health services or social services to elders or dependent adults."

Health Practitioner (WIC) "15610.37 'Health practitioner' means a physician and surgeon, psychiatrist, psychologist, dentist, resident, intern, podiatrist, chiropractor, licensed nurse, dental hygienist, licensed clinical social worker or associate clinical social worker, marriage, family, and child counselor, or any other person who is currently licensed under Division 2 (commencing with Section 500) of the Business and Professions Code, any emergency medical technician I or II, paramedic, or person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code, a psychological assistant registered pursuant to Section 2913 of the Business and Professions Code, a marriage, family, and child counselor trainee, as defined in subdivision (c) of Section 4980.03 of the Business and Professions Code, or an unlicensed marriage, family, and child counselor intern registered under Section 4980.44 of the Business and Professions Code, state or county public health or social service employee who treats an elder or a dependent adult for any condition, or a coroner."

Officers and Employees of Financial Institutions (WIC) "15630.1. (a) As used in this section, "mandated reporter of suspected financial abuse of an elder or dependent adult" means all officers and employees of financial institutions. (b) As used in this section, the term "financial institution" means any of the following: (1) A depository institution, as defined in Section 3(c) of the Federal Deposit Insurance Act (12 U.S.C. Sec. 1813(c)). (2) An institution-affiliated party, as defined in Section 3(u) of the Federal Deposit Insurance Act (12 U.S.C. Sec. 1813(u)). (3) A federal credit union or state credit union, as defined in Section 101 of the Federal Credit Union Act (12 U.S.C. Sec. 1752), including, but not limited to, an institution-affiliated party of a credit union, as defined in Section 206(r) of the Federal Credit Union Act (12 U.S.C. Sec. 1786 (r)). (c)As used in this section, "financial abuse" has the same meaning as in Section 15610.30. (d)(1)Any mandated reporter of suspected financial abuse of an elder or dependent adult who has direct contact with the elder or dependent adult or who reviews or approves the elder or dependent adult's financial documents, records, or transactions, in connection with providing financial services with respect to an elder or dependent adult, and who, within the scope of his or her employment or professional practice, has observed or has knowledge of an incident that is directly related to the transaction or matter that is within that scope of employment or professional practice, that reasonably appears to be financial abuse, or who reasonably suspects that abuse, based solely on the information before him or her at the time of reviewing or approving the document, records, or transaction in the case of mandated reporters who do not have direct contact with the elder or dependent adult, shall report the known or suspected instance of financial abuse by telephone immediately, or as soon as practicably possible, and by written report sent within two working days to the local adult protective services agency or the local law enforcement agency."

MULTIPLE REPORTERS

When two or more mandated reporters are jointly knowledgeable of a suspected instance of abuse of a dependent adult or elder, and when there is agreement among them, the telephone report may be made by one member of the group. Also, a single written report may be completed by that member of the group. Any person of that group, who believes the report was not submitted, shall submit the report.

IDENTITY OF THE REPORTER

The identity of all persons who report under WIC Chapter 11 shall be confidential and disclosed only among APS agencies, local law enforcement agencies, LTCO coordinators, California State Attorney General Bureau of Medi-Cal Fraud and Elder Abuse, licensing agencies or their counsel, Department of Consumer Affairs Investigators (who investigate elder and dependent adult abuse), the county District Attorney, the Probate Court, and the Public Guardian. Confidentiality may be waived by the reporter or by court order.

FAILURE TO REPORT

Failure to report by mandated reporters (as defined under "Reporting Party Definitions") any suspected incidents of physical abuse (including sexual abuse), abandonment, isolation, financial abuse, abduction, or neglect (including self-neglect) of an elder or a dependent adult is a misdemeanor, punishable by not more than six months in the county jail, or by a fine of not more than $1,000, or by both imprisonment and fine. Any mandated reporter who willfully fails to report abuse of an elder or a dependent adult, where the abuse results in death or great bodily injury, may be punished by up to one year in the county jail, or by a fine of up to $5,000, or by both imprisonment and fine.

Officers or employees of financial institutions (defined under "Reporting Party Definitions") are mandated reporters of financial abuse (effective January 1, 2007). These mandated reporters who fail to report financial abuse of an elder or dependent adult are subject to a civil penalty not exceeding $1,000. Individuals who willfully fail to report financial abuse of an elder or dependent adult are subject to a civil penalty not exceeding $5,000. These civil penalties shall be paid by the financial institution, which is the employer of the mandated reporter to the party bringing the action.

GENERAL INSTRUCTIONS (Continued)

EXCEPTIONS TO REPORTING

Per WIC Section 15630(b)(3)(A), a mandated reporter who is a physician and surgeon, a registered nurse, or a psychotherapist, as defined in Section 1010 of the Evidence Code, shall not be required to report a suspected incident of abuse where all of the following conditions exist:

(1) The mandated reporter has been told by an elder or a dependent adult that he or she has experienced behavior constituting physical abuse (including sexual abuse), abandonment, isolation, financial abuse, abduction, or neglect (including self-neglect).
(2) The mandated reporter is not aware of any independent evidence that corroborates the statement that the abuse has occurred.
(3) The elder or the dependent adult has been diagnosed with a mental illness or dementia, or is the subject of a court-ordered conservatorship because of a mental illness or dementia.
(4) In the exercise of clinical judgment, the physician and surgeon, the registered nurse, or the psychotherapist, as defined in Section 1010 of the Evidence Code, reasonably believes that the abuse did not occur.

Per WIC Section 15630(b)(4)(A), in a long-term care facility, a mandated reporter who the California Department of Health Services determines, upon approval by the Bureau of Medi-Cal Fraud and the Office of the State Long-Term Care Ombudsman (OSLTCO), has access to plans of care and has the training and experience to determine whether all the conditions specified below have been met, shall not be required to report the suspected incident of abuse:

(1) The mandated reporter is aware that there is a proper plan of care.
(2) The mandated reporter is aware that the plan of care was properly provided and executed.
(3) A physical, mental, or medical injury occurred as a result of care pursuant to clause (1) or (2).
(4) The mandated reporter reasonably believes that the injury was not the result of abuse.

DISTRIBUTION OF SOC 341 COPIES

Mandated reporter: After making the telephone report to the appropriate agency, the reporter shall send the original and one copy to the agency; keep one copy for the reporter's file.
Receiving agency: Place the original copy in the case file. Send a copy to a cross-reporting agency, if applicable.
DO NOT SEND A COPY TO THE CALIFORNIA DEPARTMENT OF SOCIAL SERVICES ADULT PROGRAMS BUREAU.

11166. (a) Except as provided in subdivision (d), and in Section 11166.05, a mandated reporter shall make a report to an agency specified in Section 11165.9 whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or neglect. The mandated reporter shall make an initial report to the agency immediately or as soon as is practicably possible by telephone and the mandated reporter shall prepare and send, fax, or electronically transmit a written followup report thereof within 36 hours of receiving the information concerning the incident. The mandated reporter may include with the report any nonprivileged documentary evidence the mandated reporter possesses relating to the incident.

(1) For purposes of this article, "reasonable suspicion" means that it is objectively reasonable for a person to entertain a 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 child abuse or neglect. "Reasonable suspicion" does not require certainty that child abuse or neglect has occurred nor does it require a specific medical indication of child abuse or neglect; any "reasonable suspicion" is sufficient. For the purpose of this article, the pregnancy of a minor does not, in and of itself, constitute a basis for a reasonable suspicion of sexual abuse.

(2) The agency shall be notified and a report shall be prepared and sent, faxed, or electronically transmitted even if the child has expired, regardless of whether or not the possible abuse was a factor contributing to the death, and even if suspected child abuse was discovered during an autopsy.

(3) Any report made by a mandated reporter pursuant to this section shall be known as a mandated report.

(b) If after reasonable efforts a mandated reporter is unable to submit an initial report by telephone, he or she shall immediately or as soon as is practicably possible, by fax or electronic transmission, make a one-time automated written report on the form prescribed by the Department of Justice, and shall also be available to respond to a telephone followup call by the agency with which he or she filed the report. A mandated reporter who files a one-time automated written report because he or she was unable to submit an initial report by telephone is not required to submit a written followup report.

(1) The one-time automated written report form prescribed by the Department of Justice shall be clearly identifiable so that it is not mistaken for a standard written followup report. In addition, the automated one-time report shall contain a section that allows the mandated reporter to state the reason the initial telephone call was not able to be completed. The reason for the submission of the one-time automated written report in lieu of the procedure prescribed in subdivision (a) shall be captured in the Child Welfare Services/Case Management System (CWS/CMS). The department shall work with stakeholders to modify reporting forms and the CWS/CMS as is necessary to accommodate the changes enacted by these provisions.

(2) This subdivision shall not become operative until the CWS/CMS is updated to capture the information prescribed in this subdivision.

(3) This subdivision shall become inoperative three years after this subdivision becomes operative or on January 1, 2009, whichever occurs first.

(4) On the inoperative date of these provisions, a report shall be submitted to the counties and the Legislature by the Department of Social Services that reflects the data collected from automated one-time reports indicating the reasons stated as to why the automated one-time report was filed in lieu of the initial telephone report.

(5) Nothing in this section shall supersede the requirement that a mandated reporter first attempt to make a report via telephone, or that agencies specified in Section 11165.9 accept reports from mandated reporters and other persons as required.

(c) Any mandated reporter who fails to report an incident of known or reasonably suspected child abuse or neglect as required by this section is guilty of a misdemeanor punishable by up to six months confinement in a county jail or by a fine of one thousand dollars ($1,000) or by both that imprisonment and fine. If a mandated reporter intentionally conceals his or her failure to report an incident known by the mandated reporter to be abuse or severe neglect under this section, the failure to report is a continuing offense until an agency specified in Section 11165.9 discovers the offense.

(d) (1) A clergy member who acquires knowledge or a reasonable suspicion of child abuse or neglect during a penitential communication is not subject to subdivision (a). For the purposes of this subdivision, "penitential communication" means a communication, intended to be in confidence, including, but not limited to, a sacramental confession, made to a clergy member who, in the course of the discipline or practice of his or her church, denomination, or organization, is authorized or accustomed to hear those communications, and under the discipline, tenets, customs, or practices of his or her church, denomination, or organization, has a duty to keep those communications secret.

(2) Nothing in this subdivision shall be construed to modify or limit a clergy member's duty to report known or suspected child abuse or neglect when the clergy member is acting in some other capacity that would otherwise make the clergy member a mandated reporter.

(3) (A) On or before January 1, 2004, a clergy member or any custodian of records for the clergy member may report to an agency specified in Section 11165.9 that the clergy member or any custodian of records for the clergy member, prior to January 1, 1997, in his or her professional capacity or within the scope of his or her employment, other than during a penitential communication, acquired knowledge or had a reasonable suspicion that a child had been the victim of sexual abuse that the clergy member or any custodian of records for the clergy member did not previously report the abuse to an agency specified in Section 11165.9. The provisions of Section 11172 shall apply to all reports made pursuant to this paragraph.

(B) This paragraph shall apply even if the victim of the known or suspected abuse has reached the age of majority by the time the required report is made.

(C) The local law enforcement agency shall have jurisdiction to investigate any report of child abuse made pursuant to this paragraph even if the report is made after the victim has reached the age of majority.

(e) Any commercial film and photographic print processor who has knowledge of or observes, within the scope of his or her professional capacity or employment, any film, photograph, videotape, negative, or slide depicting a

child under the age of 16 years engaged in an act of sexual conduct, shall report the instance of suspected child abuse to the law enforcement agency having jurisdiction over the case immediately, or as soon as practicably possible, by telephone and shall prepare and send, fax, or electronically transmit a written report of it with a copy of the film, photograph, videotape, negative, or slide attached within 36 hours of receiving the information concerning the incident. As used in this subdivision, "sexual conduct" means any of the following:

(1) Sexual intercourse, including genital-genital, oral-genital, anal-genital, or oral-anal, whether between persons of the same or opposite sex or between humans and animals.

(2) Penetration of the vagina or rectum by any object.

(3) Masturbation for the purpose of sexual stimulation of the viewer.

(4) Sadomasochistic abuse for the purpose of sexual stimulation of the viewer.

(5) Exhibition of the genitals, pubic, or rectal areas of any person for the purpose of sexual stimulation of the viewer.

(f) Any mandated reporter who knows or reasonably suspects that the home or institution in which a child resides is unsuitable for the child because of abuse or neglect of the child shall bring the condition to the attention of the agency to which, and at the same time as, he or she makes a report of the abuse or neglect pursuant to subdivision (a).

(g) Any other person who has knowledge of or observes a child whom he or she knows or reasonably suspects has been a victim of child abuse or neglect may report the known or suspected instance of child abuse or neglect to an agency specified in Section 11165.9. For purposes of this section, "any other person" includes a mandated reporter who acts in his or her private capacity and not in his or her professional capacity or within the scope of his or her employment.

(h) When two or more persons, who are required to report, jointly have knowledge of a known or suspected instance of child abuse or neglect, and when there is agreement among them, the telephone report may be made by a member of the team selected by mutual agreement and a single report may be made and signed by the selected member of the reporting team. Any member who has knowledge that the member designated to report has failed to do so shall thereafter make the report.

(i) (1) The reporting duties under this section are individual, and no supervisor or administrator may impede or inhibit the reporting duties, and no person making a report shall be subject to any sanction for making the report. However, internal procedures to facilitate reporting and apprise supervisors and administrators of reports may be established provided that they are not inconsistent with this article.

(2) The internal procedures shall not require any employee required to make reports pursuant to this article to disclose his or her identity to the employer.

(3) Reporting the information regarding a case of possible child abuse or neglect to an employer, supervisor, school principal, school counselor, coworker, or other person shall not be a substitute for making a mandated report to an agency specified in Section 11165.9.

(j) A county probation or welfare department shall immediately, or as soon as practicably possible, report by telephone, fax, or electronic transmission to the law enforcement agency having jurisdiction over the case, to the agency given the responsibility for investigation of cases under Section 300 of the Welfare and Institutions Code, and to the district attorney's office every known or suspected instance of child abuse or neglect, as defined in Section 11165.6, except acts or omissions coming within subdivision (b) of Section 11165.2, or reports made pursuant to Section 11165.13 based on risk to a child which relates solely to the inability of the parent to provide the child with regular care due to the parent's substance abuse, which shall be reported only to the county welfare or probation department. A county probation or welfare department also shall send, fax, or electronically transmit a written report thereof within 36 hours of receiving the information concerning the incident to any agency to which it makes a telephone report under this subdivision.

(k) A law enforcement agency shall immediately, or as soon as practicably possible, report by telephone, fax, or electronic transmission to the agency given responsibility for investigation of cases under Section 300 of the Welfare and Institutions Code and to the district attorney's office every known or suspected instance of child abuse or neglect reported to it, except acts or omissions coming within subdivision (b) of Section 11165.2, which shall be reported only to the county welfare or probation department. A law enforcement agency shall report to the county welfare or probation department every known or suspected instance of child abuse or neglect reported to it which is alleged to have occurred as a result of the action of a person responsible for the child's welfare, or as the result of the failure of a person responsible for the child's welfare to adequately protect the minor from abuse when the person responsible for the child's welfare knew or reasonably should have known that the minor was in danger of abuse. A law enforcement agency also shall send, fax, or electronically transmit a written report thereof within 36 hours of receiving the information concerning the incident to any agency to which it makes a telephone report under this subdivision.

Source:
http://www.leginfo.ca.gov/cgi-bin/displaycode?section=pen&group=11001-12000&file=11164-11174.3

Mandated Reporter Acknowledgment

By signature below I acknowledge that I have received a copy of the Mandated Reporter Information and that as a Mandated Reporter I understand the requirements of Penal Code Sections 1233.5, 11165.7. 11165.9 and 11166 as outlined and am aware of my responsibility as mandated by law.

Name of Company	Facility License #
Print Employee Name	Hire Date
Signature of Employee	Dated
Social Security #	Position/Title

SECTION	Approval date:	
Personnel	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Domestic Violence Reporting	**Revision date:**	

POLICY:

Health care providers who provide medical services for a physical condition to a patient whom he or she knows or reasonably suspects of suffering from injuries resulting from a firearm or assaultive or abusive conduct, are required to make a report (Penal Code Section 11160 et. seq.).

PROCEDURE:

I. REPORTING

Reports must be made both by telephone and in writing to a local law enforcement agency.

A **telephone report** must be made **immediately** or as soon as practically possible, without delay.

A **written report** is to be made **within two working days** of receiving the information using OCJP 920: Suspicious Injury Report Form (see attachment). The report must include the following:

- Name of the injured person, if known
- The injured person's whereabouts
- Character and extent of the person's injures
- The identity of the person who allegedly inflicted the injury

Failure to make a mandated report is a misdemeanor punishable by imprisonment in the county jail for up to six months or a fine of up to $1000, or both

Check with the local law enforcement agency of where to report if the patient was injured in another county

<u>If the battered patient is a minor then the Child Abuse and Neglect Reporting Act applies. (see Child Abuse Reporting policy and procedure)</u>

II. **MEDICAL RECORD**

The law (P.C. §11161 [b]) recommends that the medical record include the following:

- Any comments by the injured person regarding past domestic violence or regarding the name of any person suspected of inflicting the injury
- A map of the injured person's body showing and identifying injuries and bruises
- A copy of the reporting form

III. IMPORTANT CONSIDERATIONS

Sensitivity and awareness

- Reassure patient he/she is not alone and does not deserve to be treated this way
- Be careful not to imply patient is to blame
- Patients may be scared of seeking care because they do not want police involvement
- Some patients may fear reporting for other reasons (i.e., immigration status)
- There are many barriers to leaving an abusive situation (i.e., threats from the batterer, fear of financial instability, failure of police and others to effectively intervene, hope the relationship can work, feel responsible for the battering, may be embarrassed, humiliated and degraded about the abuse)

Patient Safety

- Address directly the risk of retaliation by the batterer and discuss hot the patient might protect her/himself from further abuse
- Discuss the patient's short-term option and plan, including whether the patient can safely return home
- Indicate on the reporting form any special concerns regarding how the report should be handled to maximize patient safety

Referral

- Provide patient with referrals to domestic violence services
- Assist the patient in calling a domestic crisis line if willing

Special considerations

- Patients who plan to leave with their children (applies to children for whom the abusive partner is the biological or adoptive parent) should call the shelter lines to learn how to file a "Good Cause Report" which can protect them from kidnapping charges

IV. DEFINITIONS

Assaultive or abusive conduct is defined to include a list of 24 criminal offenses, among which are murder, manslaughter, torture, battery, sexual battery, incest, assault with a deadly weapon, rape spousal rape, abuse f spouse of cohabitant, sodomy, oral copulation and an attempt to commit any of these crimes

ATTACHMENTS: Domestic Abuse & Suspicious Injury Reporting Instructions & Forms

SECTION	Approval date:	
Personnel	Approved by:	
POLICY AND PROCEDURE	**Effective date:**	
Elder & Dependent Adult Abuse Reporting	**Revision date:**	

POLICY:

Any mandated reporter who, in his or her professional capacity, or within the scope of his or her employment, has observed, suspects, or has knowledge of an incident that reasonably appears to be physical abuse (including sexual abuse), abandonment, isolation, financial abuse, abduction, or neglect (including self-neglect), or is told by an elder or a dependent adult that he or she has experienced behavior constituting physical abuse, abandonment, isolation, financial abuse, abduction, or neglect, shall report the known or suspected instance of abuse to the appropriate agency (Welfare and Institutions Code § 15630 [b]).

PROCEDURE:

I. REPORTING

Reports must be made both by telephone and in writing.

A **telephone report** must be made **immediately** or as soon as practically possible, without delay.

A written report is to be made within two business days using the SOC 341, "Report of Suspected Elder/Dependent Adult Abuse" form (see attachment)

To request a supply of SOC 341s, send a letter or fax to:

Department of Social Services Warehouse
P.O. Box 980788
West Sacramento, CA 95798-078
Fax: 916-371-3518

All of the following types of abuse must be reported:

- Physical Abuse
- Abandonment
- Isolation
- Abduction
- Financial Abuse
- Neglect (including self-neglect)

Report to the local law enforcement agency or to Adult Protective Services when abuse, neglect, or self-neglect is suspected to have occurred in the community.

Report to the local law enforcement agency or to Long Term Care Ombudsman when the abuse or neglect is suspected to have occurred in a long-term care facility.

Failure to make a mandated report is a misdemeanor punishable by imprisonment in the county jail for up to six months or a fine of up to $1,000, or both.

Any mandated reporter who willfully fails to report abuse of an elder or a dependent adult, where the abuse results in death or great bodily injury, may be punished by up to one year in the county jail, or by a fine of up to $5,000, or by both imprisonment and fine.

A single report may be made when two or more persons have knowledge of a suspected instance of abuse

II. **Exceptions to Reporting Requirement**

There are exceptions to the requirement to report:

Reporter is not aware of any independent evidence that corroborates the statement that the abuse has occurred

The elder of the dependent adult has been diagnosed with a mental illness or dementia, or is the subject of a court-ordered conservatorship because of mental illness or dementia

The reporter reasonably believes that the abuse did not occur

III. **Possible Indicators of Abuse or Neglect**

Physical Signs

Injury that has not been cared for properly

Injury that is consistent with explanation for cause

Pain from touching

Cuts, puncture wounds, burn, bruises, welts

Dehydration or malnutrition without illness-related cause

Poor coloration

Sunken eyes or cheeks

Inappropriate administration of medication

Soiled clothing or bed

Frequent use of hospital or health care/doctor shopping

Lack of necessities such as food, water, or utilities

Lack of

Personal effects, pleasant living environment, personal items

Forced isolation

Behavioral Signs

Fear

Anxiety, agitation

Anger

Isolation, withdrawal

Depression

Non-responsiveness, resignation, ambivalence

Contradictory statements, implausible stories

Hesitation to talk openly

Confusion or disorientation

Signs by Caregiver

Prevents elder from speaking to or seeing visitors

Anger, indifference, aggressive behavior toward elder

History of substance abuse, mental illness, criminal behavior, or family violence

Lack of affection toward elder

Flirtation or coyness as possible indicator of inappropriate sexual relationships

Conflicting accounts of incidents withholds affection

Withholds affection

IV. Definitions

Abandonment: The desertion or willful forsaking of an elder or dependent adult by anyone having care or custody of that person under circumstances in which a reasonable person would continue to provide care or custody

Abduction: The removal from California, and/or the restraint from returning to California, of an elder/dependent adult who does not have the capacity to consent to such removal or restraint, as well as the removal or restraint of any conservatee without the consent of the conservator or court

Abuse of an elder or a dependent adult: Physical abuse (including sexual abuse), neglect, financial abuse, abandonment, isolation, abduction, or other treatment with resulting physical harm or mental suffering, or the deprivation by a care custodian of goods or services that are necessary to avoid harm or mental suffering.

Dependent adult: Any person between the ages of 18 and 64 years, who has physical or mental limitations that restrict his or her ability to carry out normal activities or to protect his or her rights. This includes, but is not limited to, persons who have physical or developmental disabilities. It also includes those whose physical or developmental disabilities have diminished because of age as well as any 10- to 64-year-old who is admitted as an impatient to a 24-hour healthcare facility

Elder: Any person who is 65 years of age or older

Financial Abuse: A situation in which a person or entity takes, secretes, appropriates or retains the real or personal property of an elder or dependent adult to a wrongful use, or with intent to defraud, or both, OR assists another in this process. The person or entity is deemed to have committed financial abuse if such actions were taken in bad faith. A person or entity is considered to have acted in bad faith if he/they knew or should have known that the elder or dependent adult had the right to have the property transferred or made readily available to him/her or to his/her representative

Goods and services: Include but is not limited to all of the following:

- The provision of medical care for physical and mental health needs
- Assistance in personal hygiene
- Adequate clothing
- Adequately heated and ventilated shelter
- Protection from health and safety hazards
- Protection from malnutrition, under circumstances where the results include, but are not limited to, malnutrition, and deprivation of necessities or physical punishment

- Transportation and assistance necessary to secure the above goods and services

Isolation: Any of the following unless performed pursuant to a medical care plan, or unless performed in response to a reasonably perceived threat of danger to property or physical safety:

- Preventing the elder or dependent adult from receiving his/her mail or telephone calls
- Telling a caller or visitor that the elder or dependent adult does not wish to see/speak to the person, when this is contrary to the elder or dependent adult's wishes, regardless of whether he/she is mentally competent
- False imprisonment, as defined in California Penal Code, Section 236
- Physical restraint of the elder or dependent adult to prevent contact with family, friends, or concerned persons

Mental suffering: fear agitation, confusion, severe depression, or other forms of serious emotional distress that is brought about by threats, harassment, or other forms of intimidating behavior

Neglect: the negligent failure of any person having care or custody of an elder or dependent adult to exercise that degree of care that a reasonable person in a like position would exercise, including, but not limited to:

- Failure to assist in personal hygiene or in the provision of food, clothing or shelter
- Failure to provide medical care for physical and mental health needs
- Failure to protect from health and safety hazards
- Failure to prevent malnutrition or dehydration

Physical abuse: assault, battery, assault with a deadly weapon or with force likely to produce great bodily injury, unreasonable physical constraint, prolonged or continual deprivation of food or water, sexual assault or battery or rape (including spousal rape, incest, sodomy, oral copulation, or penetration by a foreign object). Physical abuse also includes the use of physical or chemical restraint or psychotropic medication either for punishment or for a period or purpose beyond which the restraint or medication was ordered by the attending, licensed physician

Reasonable suspicion: an objectively reasonable suspicion of abuse that a person should entertain, based upon the facts, and drawing upon the person's training and experience

Self-neglect: failure of the elder or dependent adult to exercise a reasonable degree of care in providing for his/her own needs in such areas as personal hygiene, food, clothing, shelter, medical and mental health care, or avoiding health and safety hazards, malnutrition or dehydration, when that failure is due to ignorance, illiteracy, incompetence, mental limitation, substance abuse or poor health

ATTACHMENTS: Elder/Dependent Adult Abuse Reporting Instructions & Forms

National Standards on Culturally and Linguistically Appropriate Services (CLAS)

The CLAS standards are primarily directed at health care organizations; however, individual providers are also encouraged to use the standards to make their practices more culturally and linguistically accessible. The principles and activities of culturally and linguistically appropriate services should be integrated throughout an organization and undertaken in partnership with the communities being served.

The 14 standards are organized by themes: Culturally Competent Care (Standards 1-3), Language Access Services (Standards 4-7), and Organizational Supports for Cultural Competence (Standards 8-14). Within this framework, there are three types of standards of varying stringency: mandates, guidelines, and recommendations as follows:

- **CLAS mandates are current Federal requirements for all recipients of Federal funds (Standards 4, 5, 6, and 7).**
- **CLAS guidelines are activities recommended by OMH for adoption as mandates by Federal, State, and national accrediting agencies (Standards 1, 2, 3, 8, 9, 10, 11, 12, and 13).**
- **CLAS recommendations are suggested by OMH for voluntary adoption by health care organizations (Standard 14).**

Standard 1
Health care organizations should ensure that patients/consumers receive from all staff member's effective, understandable, and respectful care that is provided in a manner compatible with their cultural health beliefs and practices and preferred language.

Standard 2
Health care organizations should implement strategies to recruit, retain, and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area.

Standard 3
Health care organizations should ensure that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery.

Standard 4
Health care organizations must offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation.

Standard 5
Health care organizations must provide to patients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services.

Standard 6
Health care organizations must assure the competence of language assistance provided to limited English proficient patients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the patient/consumer).

Standard 7
Health care organizations must make available easily understood patient-related materials and post signage in the languages of the commonly encountered groups and/or groups represented in the service area.

Standard 8
Health care organizations should develop, implement, and promote a written strategic plan that outlines clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services.

Standard 9
Health care organizations should conduct initial and ongoing organizational self-assessments of CLAS-related activities and are encouraged to integrate cultural and linguistic competence-related measures into their internal audits, performance improvement programs, patient satisfaction assessments, and outcomes-based evaluations.

Standard 10
Health care organizations should ensure that data on the individual patient's/consumer's race, ethnicity, and spoken and written language are collected in health records, integrated into the organization's management information systems, and periodically updated.

Standard 11
Health care organizations should maintain a current demographic, cultural, and epidemiological profile of the community as well as a needs assessment to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.

Standard 12
Health care organizations should develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and patient/consumer involvement in designing and implementing CLAS-related activities.

Standard 13
Health care organizations should ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by patients/consumers.

Standard 14
Health care organizations are encouraged to regularly make available to the public information about their progress and successful innovations in implementing the CLAS standards and to provide public notice in their communities about the availability of this information.

Title VI of the Civil Rights Act of 1964

"No person in the United States shall, on the ground of race, color or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance."

Standards to Provide "CLAS"
Culturally and Linguistically Appropriate Services

Below follows an informal summary of excerpts from the Office of Minority Health's publication entitled "Assuring Cultural Competence in Health Care: Recommendations for National Standards and an Outcomes-Focused Research Agenda."

1. Patients/consumers must receive from all staff: effective, understandable, and respectful care that is provided in a manner compatible with their cultural health beliefs and practices of preferred language.
2. Strategies should be implemented to recruit, retain, and promote a diverse staff and organizational leadership that are representative of the demographic characteristics of the service area.
3. Staff at all levels and across all disciplines should receive ongoing education and training in culturally and linguistically appropriate service delivery.
4. **Language assistance services must be offered and provided, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner, during all hours of operation.**
5. Patients/consumers must be provided verbal and written notices about their right to receive language assistance services; these notices must be in their language of preference.
6. Language assistance provided to Limited English Proficient (known as "LEP") patients must be provided by competent interpreters and bilingual staff. Family and friends should not be used for interpretation services.
7. Easily understood patient-related materials and signage must be made available/posted in languages of the commonly encountered groups represented in the service area.
8. A written strategic plan should be developed, implemented and promoted, outlining clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services.
9. Organizational self-assessments must be conducted regarding CLAS-related activities, and cultural and linguistic competence measures should be incorporated into internal audits, performance improvement programs, patient satisfaction assessments, and outcome-based valuations.
10. Data on race, ethnicity, and language difference should be collected in patient/consumer health records, integrated into the information management systems and updated periodically.
11. Current demographic, cultural, and epidemiological profiles of the communities served should be maintained, as well as needs assessments to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.
12. Participatory and collaborative partnerships with communities should be established and a variety of formal and informal mechanisms should be used to facilitate community and patient/consumer involvement in designing and implementing CLAS-related activities.
13. Conflict and grievance resolution processes must be culturally and linguistically sensitive, and capable of identifying, preventing and resolving cross-cultural conflicts or complaints by patients/consumers.
14. Information should be made public regularly regarding progress and successful innovations in implementing CLAS standards, and inform the public and the impacted communities about the availability of such information.

For Assistance or More Information, Contact SCAN Health Plan
Member Services 1-800-559-3500
Hours are 7 a.m.–8 p.m., seven days a week.
(TTY users should call 1-800-735-2929)
Member Services also has free language interpreter services available for non-English speakers.

Interpretation Service Available

English Translation:
Point to your language.
An interpreter will be called.

scan HEALTH PLAN™

SCAN provides interpreter services at no cost to SCAN members. Call SCAN Member Services Department at 1-800-559-3500 to be connected to an interpreter Monday through Friday 7:00 A.M. to 6:00 P.M.

Arabic اللغة العربية أشر الى لغتك وسننادي المترجم حالاً.	**Korean** 한국말 당신이 쓰는 말을 지적하세요. 통역관을 불러 드리겠어요.
Armenian Հայերէն Ցոյց տուէք ո՞ր մէկ լեզուն կը խօսիք՝ որպէսզի թարգմանիչ մը կանչել տանք.	**Laotian** ພາສາລາວ ຊີ້ບອກພາສາທີ່ເຈົ້າເວົ້າໄດ້ ພວກເຮົາຈະຕິດຕໍ່ນາຍພາສາໃຫ້
Cantonese 廣東話 唔該點出您講嘅語言. 等我哋幫您搵翻譯.	**Mandarin** 國語 請指認您的語言. 以便爲您請翻譯.
French Français Montrez-nous quelle langue vous parlez. Nous vous fournirons un/une interprète.	**Polish** Polski Proszę wskazać na swój język ojczysty. Tłumacz zostanie poproszony do telefonu.
German Deutsch Zeigen Sie auf Ihre Sprache. Wir rufen einen Dolmetscher an.	**Portuguese** Português Aponte seu idioma. Providenciaremos um intérprete.
Hindi हिन्दी अपनी भाषा इशारे से दिखाइये । आपके लिए दुभाषिया बुलाया जाऐगा ।	**Russian** Русский Язык Укажите, на каком языке Вы говорите. Сейчас Вам вызовут переводчика.
Hmong Hmoob Thov taw tes rau koj yam lus. Peb yuav hu ib tug neeg txhais lus rau koj.	**Spanish** Español Señale su idioma. Se llamará a un intérprete.
Italian Italiano Faccia vedere qual è la sua lingua. Un interprete sarà chiamato.	**Tagalog** Tagalog Pakituro po ninyo ang inyong wika. Magpapatawag kami ng interpreter.
Japanese 日本語 あなたの話す言葉を指さしてください。 通訳を呼びます。	**Thai** ภาษาไทย ช่วยชี้ให้เราดูหน่อยว่าภาษาไหนคือภาษาที่ท่านพูด แล้วเราจะจัดหาล่ามให้ท่าน
Khmer (Cambodian) ខ្មែរ (កម្ពុជា) សូមចង្អុលភាសាអ្នក យើងនឹងហៅអ្នកបកប្រែមកជូន	**Vietnamese** Tiếng Việt Chỉ rõ tiếng bạn nói. Sẽ có một thông dịch viên nói chuyện với bạn ngay.

♻ Printed on recycled paper 12/04

Poster provided by Language Line Services ©2004 • 1 800 752-6096 • www.LanguageLine.com
Over-the-phone interpretation and document translation in more than 150 languages.

Language Line services

Request/Refusal Form for Interpretive Services

Patient name: _____

Primary Language: _____

☐Yes, I am requesting interpretive services.

Language(s): _____

☐I prefer to use my family or friend as an interpreter.

☐No, I do not require interpretive services.

☐N/A

Please explain: _____

_____

_____

_____

_____ _____

Patient signature Date

*Please place in patient's medical record.

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Cultural and Linguistics	Revision date:	

CULTURALLY COMPETENT SERVICES

POLICY:

All patients shall be assessed for cultural and ethnic characteristics that may affect behaviors and treatment. All clinical staff shall demonstrate understanding of cultural and ethnic variances related to illness and care of patients. Every effort shall be made to adapt services to meet specific needs within cultural and ethnic differences. These differences may affect communication, activities of daily living, food practices, beliefs about medicines and healing, responses to pain and touch, birth and death rituals, family relationships and spiritual health practices.

PROCEDURE:

1. All staff shall demonstrate sensitivity to different culture and ethnic backgrounds especially when caring for patients with different cultural and ethnic needs.

2. Providing services to persons with different cultural and ethnic backgrounds:

    a. The most effective tool in working with patients from other cultural and ethnic background is respect. Patients may pick up quickly when there is a tone of condescension of judgement that comes from a staff person. Negative non-verbal communication is powerful in rendering ineffective care. Be open to understanding the patient's unique perspective and experiences.
    b. Accept responsibility for any misunderstanding that may occur rather than expecting the patient to bridge the cultural and ethnic gap.
    c. Do not assume anything about anyone, even though you are "well-read" about the practices of a particular group. Be willing to admit that you do not know. Remember, you are in an insider to your own culture and an outsider to another ethnicity and culture.
    d. If a staff or provider has difficulty working with patients from another culture, that staff or provider must assess and address those barriers when working with patients from that culture.
    e. The more conscious you are of your own biases, the more open minded and understanding you can be.
    f. Assume there are good reasons for why patients do what they do. There are often a variety of factors that can influence decisions patients make that you may not be privy to.
    g. Listen actively and carefully. Listen not only for factual information but closely watch the patient's reaction. Notice what the patient asks about. Stop talking as soon as the patient seems they have something to say. Accept silence as a natural part of conversation.
    h. Give non-judgmental feedback to be sure you heard what you thought you heard. Be careful about how literal you take things and how literal your statements might be taken.
    i. Expect to enjoy meeting patients with experiences different from your own. There may be times when we seek out the familiar people and things but cultural venturing can be stimulating and gratifying.
    j. Notice and remember what patients call themselves. Be a bit on the formal side at first in language and behavior until you are more acquainted. Be sure to remain professional whether more formal or more casual.
    k. If it appears to be appreciated, act as a cultural guide-coach to the patient. Look for ethnic and cultural guides or coaches, to help you put things in perspective. Ask

questions. Some people appreciate interest in their experiences. Be careful, though, because asking questions may have a judgement tone, implying that the thing you ask is not acceptable.

l. If someone speaks more loudly than you, or stands more still, adjust your behavior. Watch cultural groups interacting among themselves, and learn what their norms are.

3. What Successful Communicators Never Do

   a. Never make assumptions based on a person's appearance, name, and membership in a group. Do not expect people of a group to look, act and think alike.
   b. Never show amusement or shock at something that is strange to you.
   c. Never imply that the established way of doing things is the only way or the best way. This refers to lifestyles, not laws, rules or regulations.

LINGUISTIC SERVICES

POLICY:

According to the Department of Justice, "People who are completely bilingual are fluent in two languages. They are able to conduct the business of the workplace in either of those languages. Bilingual staff can assist in meeting the Title VI and Executive Order 13166 requirement for federally conducted and federally assisted programs and activities to ensure meaningful access to LEP (limited English proficient) persons."

"One of the primary ways that bilingual staff can be used as part of a broader effort to ensure meaningful access is to have them conduct business with the agencies' LEP clients directly in the clients' primary language." "This is sometimes called "monolingual communication in a language other than English."

An interpreter is defined as a person who provides immediate communication of meaning from one language (the source language) into another (the target language). An interpreter is usually a third party who interprets between speakers who speak different languages.

The site has 24-hour access to interpreter services for non-/LEP members and the hearing impaired.

PROCEDURE:

1. Staff shall ensure that interpreter services are made available in identified threshold languages specified for location of site.

2. All personnel providing language interpreter services on site are trained/competent in medical interpretation.

3. The provider/designee shall assess interpreter skills and capabilities of their staff providing interpreter services using at least one or more of the following (please check all that apply):
   - ☐ Assessment of interpreter skills may include written or oral assessment of bilingual skills;
   - ☐ Documentation of the number of years of employment as an interpreter or translator;
   - ☐ Documentation of successful completion of a specified type of interpreter training programs, i.e., medical, legal, court, or semi-technical; OR
   - ☐ Other reasonable alternative documentation of interpreter capability as specified below:

     _____
     _____

4. Staff shall document in the medical record any request for, or refusal of, language interpreter services and the name of the interpreter.

5. The PCP shall ensure that 24-hour language and hearing-impaired interpreter services are available for all members either through telephone/video language services or interpreters on site.

The following lists the threshold languages (other than English) spoken by non-/LEP members on site:

_____

_____

The following table lists all bilingual providers and staff on site who are deemed capable and competent as interpreters based on the assessment above. Please use additional pages as needed.

Name of Provider/Staff	Title	Language(s) of fluency other than English

KNOW THE RIGHTS THAT PROTECT INDIVIDUALS WITH DISABILITIES FROM DISCRIMINATION

OFFICE FOR CIVIL RIGHTS

What is Section 504?

Section 504 is part of the Rehabilitation Act of 1973: a Federal law that protects individuals from discrimination based on disability. Under this law, individuals with disabilities may not be excluded from or denied the opportunity to receive benefits and services from certain programs.

What is Title II of the Americans with Disabilities Act?

Title II of the Americans with Disabilities Act (ADA) is another law that prohibits disability discrimination. It applies to all state and local government agencies and offers protections similar to Section 504.

To whom do these laws apply?

Section 504 applies to entities that receive financial assistance from any Federal department or agency, including the U.S. Department of Health and Human Services (HHS). These entities include many hospitals, nursing homes, mental health centers and human service programs. The Office for Civil Rights (OCR) at HHS, ensures that entities receiving federal financial assistance comply with these laws. Title II of the ADA applies to all state and local government agencies, whether or not they receive Federal financial assistance.

Who qualifies as an individual with a disability?

Section 504 defines an individual with a disability as a person with a physical or mental impairment that substantially limits one or more major life activities. Major life activities include caring for one's self, walking, seeing, hearing, speaking, breathing, working, performing manual tasks and learning.

Some examples of impairments that may substantially limit major life activities include: HIV/AIDS, blindness or low vision, cancer, deafness, diabetes, heart disease, intellectual disabilities and mental illness.

This also includes people who have a history of a physical or mental impairment that substantially limits one or more major life activities or who have been subjected to a discriminatory action because of an actual or perceived physical or mental impairment whether or not the impairment limits or is perceived to limit a major life activity.

Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW.
H.H.H. Building, Room 509-F
Washington, D.C. 20201

TELEPHONE
1-800-368-1019

E-MAIL
ocrmail@hhs.gov

TDD
1-800-537-7697

www.hhs.gov/ocr

How are individuals with disabilities protected by these laws?

Public entities and those receiving HHS funding may not:

- Refuse to allow a person with a disability to participate in, or benefit from, their services, programs or activities because the person has a disability.
- Apply eligibility criteria for participation in programs, activities and services that screen out or tend to screen out individuals with disabilities, unless they can establish that such criteria are necessary for the provision of services, programs or activities.
- Provide services or benefits to individuals with disabilities through programs that are separate or different, unless the separate programs are necessary to ensure that the benefits and services are equally effective.

Public entities and those receiving HHS funding must:

- Provide services, programs and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities.
- Make reasonable modifications in their policies, practices and procedures to avoid discrimination on the basis of disability, unless they can demonstrate that a modification would fundamentally alter the nature of their service, program or activity.
- Ensure that their programs, activities and services are accessible to and readily usable by individuals with disabilities.
- Provide auxiliary aids at no additional cost to individuals with disabilities, where necessary, to ensure effective communication with individuals with hearing, vision or speech impairments. Auxiliary aids include, but are not limited to, services or devices such as: qualified interpreters on-site or through video remote interpreting (VRI) services, note takers, assistive listening devices, television captioning and decoders, telecommunication products and systems, qualified readers, taped texts, Brailled materials, and large print materials.

How to file a complaint of discrimination with the Office for Civil Rights (OCR)

If you believe that you or someone else has been discriminated against because of disability by an entity receiving financial assistance from HHS, you or your legal representative may file a complaint with OCR. Complaints must be filed within 180 days from the date of the alleged discrimination.

You may send a written complaint or you may complete and send OCR the Complaint Form available on our webpage at www.hhs.gov/ocr. The complaint form is also available on our webpage in a number of other languages under the Civil Rights Information in Other Languages section.

The following information must be included:

- Your name, address and telephone number.
- You must sign your name on everything you write. If you file a complaint on someone's behalf — e.g. spouse, friend, client, etc. — include your name, address, telephone number, and statement of your relationship to that person.
- Name and address of the institution or agency you believe discriminated.
- When, how and why you believe discrimination occurred.
- Any other relevant information.

If you mail the complaint, be sure to send it to the attention of the regional manager at the appropriate OCR regional office. OCR has ten regional offices and each regional office covers specific states. Complaints may also be mailed to OCR Headquarters at the following address:

Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW.
H.H.H. Building, Room 509-F
Washington, D.C. 20201

To learn more:
Visit us online at www.hhs.gov/ocr
Call us toll-free at 1-800-368-1019
Email us: ocrmail@hhs.gov
TDD: 1-800-537-7697

Language assistance services for OCR matters are available and provided free of charge. OCR services are accessible to persons with disabilities.

www.hhs.gov/ocr

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Disability Rights and Provider Obligations	Revision date:	

POLICY:

Section 504 of the Rehabilitation Act of 1973 is a national law that protects qualified individuals from discrimination based on their disability. The nondiscrimination requirements of the law apply to employers and organizations that receive financial assistance from any Federal department or agency, including the U.S. Department of Health and Human Services (DHHS).

Section 504 forbids organizations and employers from excluding or denying individuals with disabilities an equal opportunity to receive program benefits and services. It defines the rights of individuals with disabilities to participate in, and have access to, program benefits and services.

Under this law, individuals with disabilities are defined as persons with a physical or mental impairment which substantially limits one or more major life activities. People who have a history of, or who are regarded as having a physical or mental impairment that substantially limits one or more major life activities, are also covered. Major life activities include caring for one's self, walking, seeing, hearing, speaking, breathing, working, performing manual tasks, and learning. Some examples of impairments which may substantially limit major life activities, even with the help of medication or aids/devices, are: AIDS, alcoholism, blindness or visual impairment, cancer, deafness or hearing impairment, diabetes, drug addiction, heart disease, and mental illness.

Section 504 prohibitions against discrimination apply to service availability, accessibility, delivery, employment, and the administrative activities and responsibilities of organizations receiving Federal financial assistance. A recipient of Federal financial assistance may not, on the basis of disability:

- Deny qualified individuals the opportunity to participate in or benefit from federally funded programs, services, or other benefits.
- Deny access to programs, services, benefits or opportunities to participate as a result of physical barriers.

Section 1557 is the nondiscrimination provision of the Affordable Care Act (ACA). The law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities that receive Federal financial assistance or are administered by an Executive agency or any entity established under Title I of the ACA. Section 1557 has been in effect since enactment of the ACA. The Section 1557 final rule applies to recipients of financial assistance from the Department of Health and Human Services (HHS), the Health Insurance Marketplaces and health programs administered by HHS.

The final rule is consistent with existing directives implementing the requirements under the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973. It requires effective communication, including through the provision of auxiliary aids and services; establishes standards for accessibility of buildings and facilities; requires that health programs provided through electronic and information technology be accessible; and requires covered entities to make reasonable modifications to their policies, procedures, and practices to provide individuals with disabilities access to a covered entity’s health programs and activities.

The final rule requires all covered entities to post a notice of consumer civil rights; covered entities with 15 or more employees are also required to have a civil rights grievance procedure and an employee designated to coordinate compliance. Under a new requirement, covered entities are required to post information telling consumers about their rights and telling consumers with disabilities and consumers with limited English proficiency (LEP) about the right to receive communication assistance.

According to Title 28, Code of Federal Regulations (CFR), section 35.151, 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. 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. The site shall 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.

PROCEDURE:

1. A notice of consumer civil rights shall be posted in a prominent location in the clinic.
2. The clinic has the following safety accommodations available for physically disabled persons or has an alternative plan in place for making program services available to persons with physical disabilities (see checked items that apply):
    - ☐ 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; or reasonable alternative if the provider has no control over availability of accessible parking within the lot or nearby street spaces for persons with disabilities: _____ _____
    - ☐ Pedestrian ramps with a clear and level landing at the top and bottom of all ramps and on each side of an exit door – if the clinic has multiple levels.
    - ☐ Exit and exam room doorway openings have minimum opening of 32 inches with the door open at 90 degrees to allow for clear passage of a person in a wheelchair; or reasonable alternative: _____
    - ☐ Door hardwares are operable with a single effort without requiring ability to grasp hardware (latch or push-bars instead of door knobs)
    - ☐ Effort to operate interior doors do not exceed 5 pounds of pressure
    - ☐ Furniture and other items do not obstruct exit doorways or interfere with door swing pathway
    - ☐ Accessible passenger elevator for multi-level floor accommodation; or reasonable alternative: _____
    - ☐ Clear floor space (at least 30-in. x 48-in.) for wheelchair in waiting area and exam room to accommodate a single, stationary adult wheelchair and occupant; and a minimum clear space of 60-inch diameter or square area to turn a wheelchair; or reasonable alternative: _____
    - ☐ Wheelchair accessible restroom facilities are available; or reasonable alternative: _____
    - ☐ Wheelchair accessible handwashing facilities are available; or reasonable alternative: _____
    - ☐ A 24-hour language and hearing-impaired interpreter services are available for all members either through telephone/video language services or interpreters on site
    - ☐ Other accommodations or specialized equipment (i.e., heigh adjustable exam tables, wheelchair accessible weight scales, signage in raised letters and Braille, etc.): _____ _____
3. If any patient feels that they have been subject to discrimination in health care or health coverage, they may file a complaint of discrimination under Section 1557. They are encouraged to visit the Office of Civil Right's (OCR's) website at www.hhs.gov/ocr to file a complaint or to request a complaint package, or call OCR's toll free number at (800) 368-1019 or (800) 537-7697

(TDD) to speak with someone who can answer their questions and guide them through the process. OCR's complaint forms are available in a variety of languages. Individuals can also file lawsuits under Section 1557.

4. For sites with 15 or more employees – A civil rights grievance procedure is followed:
    a. The employee designated to coordinate compliance is: _____
    b. All civil rights discrimination complaints shall be processed following the site's *Member Grievances/Complaints* policy.
5. All site personnel shall receive 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.
6. Training content includes information about physical access, reasonable accommodations, policy modifications, and effective communication in healthcare settings.

RESOURCES:

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
https://www.ecfr.gov/search

ATTACHMENTS:

Notice of Nondiscrimination (sample)
Statement of Nondiscrimination (sample)
Physical Accessibility Review Survey Information and Tools

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Access to Care 24/7	Revision date:	

POLICY:

The site shall have a provision for appropriate, coordinated access to health care services 24 hours a day, seven (7) days a week.

PROCEDURE:

A. The staff shall ensure that current clinic office hours are posted within the office or readily available upon request.

B. The PCP shall ensure that the following current site-specific resource information are available to site personnel:
   1. Physician office hour schedule(s),
   2. Group and/or Plan-specific systems for after-hours urgent care,
   3. Emergent provider/on-call coverage available 24 hours a day, 7 days per week, and
   4. A system for providing follow-up care.

C. When the PCP is not on site during regular office hours, personnel are able to contact the provider (or covering provider) at all times by telephone, cell phone, pager, etc.

D. During after-hours or when the PCP is not on site during regular office hours, the PCP (or covering provider) shall respond to urgent/emergent member matters within 30 minutes.

E. Telephone answering machine, voice mail system or answering service are used whenever office staff does not directly answer phone calls.

F. Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated to ensure functionality and validity of information:
   - ☐ Monthly
   - ☐ Quarterly
   - ☐ Other: _____

G. After-hours emergent, urgent and routine care instructions/clinic information are made available to patients. The site has the following answering service/machine greeting and instructions (if different from below, see attached script):

   "*You have reached the office of* _____ (Clinic/PCP name). *Our office is currently closed. If this is a life-threatening emergency, hang up and call 911 or go to the nearest emergency room. If this is an urgent matter and you need to speak to the doctor, please call* _____ (provider's after-hours phone or pager number). *Your call will be returned within 30 minutes. For routine matters such as appointments or prescription refills, please leave a message after the tone. Please be sure to include your name and your telephone number with the area code. We will return your call during our normal office hours. Our normal office hours are* _____ (day) *through* _____ (day), _____ (opening time) *until* _____ (closing time)."

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Triage	Revision date:	

POLICY:

The site shall have sufficient health care personnel to provide timely, appropriate health care services. Triage is the sorting and classification of information to determine priority of need and proper place of treatment. Telephone triage is the system for managing telephone callers during and after office hours.

PROCEDURE:

A. The PCP shall ensure that appropriate personnel handle emergent, urgent and medical advice telephone calls. This includes licensed medical personnel such as a Certified Nurse Mid-Wives, Nurse Practitioners, Registered Nurses or Physician Assistants. Licensed Vocational Nurses (LVN) shall not perform triage independently (MCPB letter 92-15). 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 (MCPB Letter 92-15). 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 (Title 16, §1366 (b)).

B. Staff shall ensure that a telephone answering machine, voice mail system or answering service is utilized whenever office staff does not directly answer phone calls.
   1. The providers are responsible for the answering service they utilize. If a member calls after hours or on weekends due to possible medical emergency, the practitioner is responsible for authorization of or referral to, emergency care given by the answering service. There shall be a greeting that immediately state the following or similar instruction to the member: "If this is a life-threatening emergency, hang up and call 911 or go to the nearest emergency room."
   2. Answering service staff handling member calls cannot provide telephone medical advice if they are not a licensed, certified or registered health care professional. Staff members may ask questions on behalf of a licensed professional in order to help ascertain the condition of the member so that the member can be referred to licensed staff; however, they are not permitted, under any circumstance, to use the answers to questions in an attempt to assess, evaluate, advise, or make any decision regarding the condition of the member, or to determine when a member needs to be seen by a licensed medical professional.
   3. Unlicensed personnel responsible for answering telephone calls shall have clear instructions on parameters related to the appropriate questions to ask and responses to give to members in order to assist a licensed provider in triaging the member for appropriate care.

C. Staff shall ensure that the telephone system, answering service, recorded telephone information, and recording devices are periodically checked and updated (see *Access to Care 24/7 Policy* for periodic monitoring schedule). The Health Plan encourage answering services to follow these steps when receiving a call:

1. Inform the member that if they are experiencing a medical emergency, they should hang up and call 911 or proceed to the nearest emergency medical facility.
2. Ask the member according to the PCP's or Physician Group's established instructions (who, what, when, and where) to assess the nature and extent of the problem.
3. Contact the on-call physician with the facts as stated by the member.
4. After office hours, physicians are required to return telephone calls and pages within 30 minutes. If an on-call physician cannot be reached, direct the member to a medical facility where emergency or urgent care treatment can be given.

SECTION	Approval date:	
Office Management	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Appointments and Patient Recall	Revision date:	

POLICY:

A system is established that 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.

PROCEDURE:

A. Staff shall notify and remind members of scheduled appointments and/or preventive screening appointments.

B. The PCP shall provide an initial health assessment (IHA) for each adult member within 120 days of the date of enrollment, unless the member's PCP determine that the member's medical record contains complete and current information consistent with the assessment requirements within periodicity time requirements.

C. The Health Plan shall follow its procedure to advise the plan members of the availability and value of scheduling an IHA appointment. The Health Plan will provide monthly eligibility reports to PCPs, listing the members' names, addresses, and telephone numbers. If a member or guardian refuses to have an IHA performed, this information shall be documented in the member's medical record.

D. Staff shall follow up on missed and/or canceled appointments via mail or phone. At least three attempts shall be made and documented in the patient's record.

E. The PCP shall ensure that appointments are designed according to the patient's clinical needs and within the following timeliness standards:

1. Urgent Care: within 24 hours
2. Prenatal Care: within 7 days
3. Non-urgent Care: within 14 days
4. Well Baby Visits: within 14 days

Pharmaceuticals Storage, Handling and Dispensing

PURPOSE: To store and dispense drugs in accordance with State, Federal and Local distribution laws and regulations.

PERSONNEL: Physicians, Non-Physician Practitioners, Nurses, and Medical Assistants

DEFINITIONS:

Drug: Any chemical compound, remedy or noninfectious biological substance, the action of which is not solely mechanical, which may be administered to patients by any route as an aid for the diagnosis, treatment, or prevention of disease or other abnormal condition, for the relief of pain and suffering, or to control or improve any physiological or pathological condition.

Drug Administration: The action, which a single dose of prescribed drug is given to the patient.

Drug Dispensing: The interpretation of an order for a drug, the proper selection, measuring, packaging, labeling and issuance of the drug.

Storage and Handling

1. All drugs will be well organized and stored in specifically designated cupboards, cabinets, closets or drawers.
2. Drugs will be stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, purity of the drug product is not affected. Room temperature drugs should not be stored above 86° F (30° C)
3. Prescription, sample, over the counter drugs, prescription pads and hypodermic needles will be securely stored in a lockable space (cabinet or room) within the office/clinic.
4. Keys to locked storage area will be available only to staff authorized by the physician to have access. (During business hours, the drawer, cabinet or room containing drugs or medication supplies may remain unlocked **ONLY** if there is no access to the area by unauthorized persons. Whenever drugs or supplies are unlocked, authorized clinic personnel must remain in the immediate area **at all times**. At all other times they will be securely locked.
5. Drugs will be prepared in a clean area, or "designated clean" area if prepared in a multipurpose room. Vaccines will not be stored in the door of refrigerator or freezer.
6. Drugs for external use in liquid, tablet, capsule or powder form shall be stored separately from medications for internal use.
7. Drugs and immunobiologics requiring refrigeration will be kept in refrigerators that shall be maintained between 2º C (35ºF) and 8º C (46ºF).
8. Drugs and immunobiologics requiring freezing, will be kept in freezers that shall be maintained at 5º F or -15º C, or lower.
9. **Daily** temperature readings of medication refrigerator and medication freezer will be documented. (See Appendix A).
10. Items other than medications in refrigerator/freezer will be kept in a secured, separate compartment from drugs.
11. Drugs must be kept separate from food, lab specimens, and other items that may potentially cause contamination.
12. Tests reagents, germicides, disinfectants and other household substances shall be stored separately from drugs.

Expiration Date Compliance

1. The manufacturer's expiration date must appear on the labeling of all drugs. All prescription drugs not bearing the expiration date are deemed to have expired.
2. If a drug is to be reconstituted at the time of dispensing, its labeling must contain expiration information for both the reconstituted and unconstituted drug.
3. Expired drugs will not be distributed or dispensed.
4. All drugs including stock, vaccine, sample, emergency, controlled, infant and therapeutic formulas will be checked for expiration monthly and written documentation will be maintained. (See Appendix B).

Controlled Substances

1. A dose-by-dose controlled substance distribution log will be maintained, with written records that include: provider's DEA number, name of medication, original quantity of drug, dose, date, name of patient receiving the drug, name of authorized person dispensing drug and number of remaining doses. (See Appendix C, Pages 1&2).
2. Controlled substances will be stored separately from other drugs in a securely locked, substantially constructed cabinet.
3. Controlled 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.
4. Personnel with authorized access to controlled substances include physicians, dentists, podiatrists, physician's assistants, licensed nurses and pharmacists.

Disposal and Dispensing

1. Drugs will be disposed of appropriately. Drugs may be returned to the manufacturer or disposed of in medical waste. (See disposal of controlled substances below).
2. Drugs will be dispensed only by a physician, pharmacists or other persons (e.g.; NP, CNM, RN, PA) lawfully authorized to dispense medications, upon the order of a licensed physician or surgeon.
3. Personnel such as medical assistants, office managers, and receptionists will not dispense drugs.
4. Drugs will not be offered for sale, charged or billed to Medi-Cal members.
5. All drugs that are dispensed will be labeled and will include the following:

   Provider's name, patient's name, drug name, dose, frequency, route, quantity dispensed, and manufacturer's name and lot number.

   Dispensing containers will not be cracked, soiled or without secure closures. 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 and no charge is made to the patient.

   All pre-filled syringes must be individually labeled with date, medication name, and dosage.
6. All drugs that are administered or dispensed will be recorded in the medical record.
7. Disposable of Controlled Substances:

   - The DEA requires providers to maintain documentation of disposal of all controlled substances.
   - Provider may return the controlled drugs to the drug manufacturer.
   - Controlled drugs may be sent to a DEA registered disposal firm (reverse distributor) for destruction.
   - Providers may conduct their own drug destruction if the DEA had previously authorized them to do so. Those authorizations will remain in effect until rescinded, revoked, or procedures are changed.

Source: www.ccah-alliance.org/FReview/Clinical_Services/1_**Pharmaceuticals**

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**

The " Basic Rights" of medication/vaccine administration:

#1 The right patient

You do not want to administer the medication or vaccine dose on your medication or vaccine tray to the wrong patient! Make sure you are administering the right person by verifying the patient's name and date of birth before you administer medication or vaccine to them. And while you are at it, make sure you have screened for contraindications and precautions for that medication or vaccination.

#2 The right vaccine (and diluent) / medication

Errors have occurred administering the wrong vaccine or medication product to a patient. Check the vial label three times to be sure you have chosen the correct vaccine product (and diluent, when applicable). Check the expiration date of the vaccine (and diluent) before using to be sure they are not out of date.

#3 The right dosage

Errors have been made giving a wrong amount of medication or vaccine to a person, such as giving a pediatric vaccine to an adult or vice versa. Medication/Vaccine dosages are usually guided by the patient's age (and are not based on the patient's weight). Check the package insert or an appropriate guidance document (see resources below) to confirm the appropriate dose for your patient's age.

#4 The right route, needle, and technique

Errors are often made administering vaccines or medication using the wrong route, needle, or technique. Be sure you know the appropriate route of administration (oral, intranasal, subcutaneous, intramuscular (IM), or intradermal) for the vaccine you are using. Needle selection should be based on the prescribed route, size of the individual, volume and viscosity of vaccine, and injection technique. Follow CDC guidance to confirm you are adhering to the correct route, needle, and technique. Deviation from recommendations can reduce vaccine efficacy or increase local adverse reactions.

#5 The right time

Sometimes vaccines are not administered according to the official U.S. immunization schedule. They are given to the wrong age patient, or they are administered earlier than they should be. Be sure the patient is the appropriate age for the vaccine you plan to administer and that the appropriate interval has passed since a previous dose of the same vaccine or between two live vaccines. For medication, check the frequency of the ordered medication. Double-check that you are giving the ordered dose at the correct time. Confirm when the last dose was given.

SECTION	Approval date:	
Clinical Services	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Pharmaceutical & Vaccine Services	Revision date:	

POLICY:

The site shall maintain competent, efficient, and ethical Pharmaceutical Services according to state and federal statutes for the health and safety of its patients.

PROCEDURE:

I. Drugs and medication supplies are maintained secure to prevent unauthorized access:

A. All drugs (including sample and over the counter), medication supplies, prescription pads, and hazardous substances are securely stored in a lockable space (e.g., a room, closet, cabinet, drawer, etc.) within the office/clinic (CA B&P Code, §4051.3). Keys to the locked storage area are available only to staff authorized by the physician to have access (16 CCR, Chapter, Division 3, §1356.32).
- During business hours, the lockable space may remain unlocked ONLY if there is no access to this area by unauthorized persons and authorized clinic personnel remain in the immediate area at all times. At all other times, all prescription pads and hazardous substances must be securely locked.

B. Controlled drugs are stored separately from other drugs, in a secured, lockable space accessible ONLY to authorized personnel (including physicians, dentists, podiatrists, physician assistants, licensed nurses and pharmacists) (Control Substance Act, CFR §1301.75). There is no need for the controlled substances to be double locked
- Controlled Substances include all Schedule I, II, III, IV, and V substances listed in the CA Health and Safety Code, §§11053-11058.

C. A dose-by-dose controlled substance distribution log shall be maintained to include the following:
    a. Date
    b. Provider's DEA number
    c. Name of controlled substance
    d. Original quantity of controlled substance
    e. Dose administered, Number of doses remaining
    f. Name of patient receiving controlled substance
    g. Name of authorized person dispensing controlled substance

II. Drugs are handled safely and stored appropriately.

A. Preparation:
- Drugs are prepared in a clean area, or a "designated clean" area if prepared in a multipurpose room.
- Drugs or medication supplies are considered "adulterated" if it contains any filthy, putrid, or decomposed substance, or if it has been prepared, packed, or held under unsanitary conditions (21 USC §351).

B. Storage:

- Items other than medications in refrigerator/freezer are kept in a secured, separate, compartment from drugs, as these items may potentially cause contamination.
- Drugs are stored separately from test reagents, germicides, disinfectants, and other household substances.
- 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 (21 CFR, §211.142). Room temperature where drugs are stored does not exceed 30ºC (86ºF) (Title 22, §75037(d)).

C. Immunobiologics:

- Vaccines are placed in a refrigerator or freezer (**not** on the door) immediately upon receipt on site and are stored according to specific instructions in the package insert for each vaccine.
- Vaccines, such as DTP, DTaP, DT, Td, Hep A, Hep B, Enhanced Inactive Polio (E-IPV), and Pneumococcal, are kept in a refrigerator maintained at 2º-8 ºC or 36 º-46 ºF (at time of visit). MMR and varicella are protected from light at all times. Oral polio vaccine (OPV), MMR, MMRV, and varicella vaccines are stored in a freezer maintained at -15 ºC, or 5 ºF, or lower (at time of visit). Failure to adhere to recommended specifications for storage and handling of Immunobiologics could make these products impotent.
- A written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer is available on site (see Attachments).
- Site personnel are able to verbalize the procedures in the plan used to promptly respond to out of range temperatures.
- 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 (data loggers), calibrated at least every 2 years, to monitor vaccine storage unit temperatures. Data loggers should have a minimum accuracy of +/- 1°F (0.5°C), be equipped with buffered probe, an active temperature display outside of the unit, and the capacity for continuous monitoring and recording where the data can be routinely downloaded. A back-up device should be readily available for emergency vaccine transport or when primary data logger is sent in for calibration.

D. Hazardous substances (Substances that are physical or health hazards):

- Safety practices on site are followed in accordance with current/updated CAL-OSHA standards.
- The manufacturer's label is not removed from a container as long as the hazardous material (or residue from the material) remains in the container.
- All portable containers of hazardous chemicals and secondary containers (into which hazardous substances are transferred or prepared) require labeling. Hazardous substances are appropriately labeled with the following information:
  a. Identity of hazardous substance
  b. Description of hazard warning: can be word, pictures, symbols
  c. 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.******

- Site has method(s) in place for drug and hazardous substance disposal (see C.5.).

III. Drugs are administered or dispensed according to State and Federal drug distribution laws and regulations.

A. Drug Dispensing and Administration:

- Drug dispensing is in compliance with all applicable State and Federal laws and regulations. Drugs are not offered for sale, charged, or billed to Medi-Cal members (Business and Professions Code, Article 13, §4193).
- Criteria for selecting pharmaceutical manufacturers and suppliers shall be established to ensure that patients receive pharmaceuticals and related supplies of the highest quality.
- The clinic shall govern the activities of manufacturers' representatives or vendors of drug products (including related supplies and devices) within the ambulatory care setting. Representatives should not be permitted access to patient care areas and should be provided with guidance on permissible activities. All promotional materials and activities shall be reviewed and approved by the provider.
- Adequate inventory controls shall be maintained to allow proper inventory levels of medications based on utilization.
- A list of drugs available for dispensing or administration in the clinic shall be maintained (see Attachments).
- Each prescription medication is dispensed in a container that is not cracked, soiled, or without secure closures (Title 22, CCR, §75037 (a)).
- Drugs are dispensed **ONLY** by a physician, pharmacist, or other persons (i.e., NP, CNM, RN, PA) lawfully authorized to dispense medication upon the order of a licensed physician or surgeon. Personnel, such as medical assistants, office managers, and receptionists, **DO NOT DISPENSE DRUGS**.
- A record of all drugs dispensed is entered in the patient's medical record.
- 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 (CA Business and Professions Code, §§ 4170-4171).
- Administration of medications ordered by the licensed practitioner may be completed by the MA using the following procedures:
  a. Prepare medication in a clean area
  b. Have the ordering practitioner or another licensed practitioner (i.e., MD, NP, PA, CNM, RN, LVN) verify the medication and dosage prior to administration of the drug by:
     - Showing the bottle or vial and medicine cup or syringe to the verifying practitioner
     - Show the patient's chart and original medication order to another verifying practitioner when the ordering practitioner is not available
     - Administer to the patient only after a licensed practitioner has checked the prepared medication for the correct medication, correct dose, correct route, and the appropriate time; and the patient's identity is verified.
  c. To help reduce the risk of medication errors, staff shall confirm the patient's identity prior to administration by asking the patient/parent to confirm the patient's name and date of birth.
  d. Drugs and vaccines are prepared and drawn only prior to administration.
  e. Unused prefilled syringes shall 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) shall be discarded at the end of the clinic day.

  NOTE: No MA may administer any anesthetic agent or any medication mixed with an anesthetic agent (e.g., Rocephin diluted with Xylocaine).
- All vaccines administered in the clinic shall be reported by the clinic to an immunization registry (i.e., California Immunization Registry or "CAIR")

B. Vaccine Information Statements (VIS):

- Since 1994, the National Childhood Vaccine Injury Act (§2126 of the Public Health Services Act) mandates that parents/guardians or adult patients be informed before vaccines are administered. Health care providers **must** give a copy of the most recent VIS to patients prior to each vaccination dose of ALL vaccines (i.e., DTaP, Td/Tdap, MMR, Influenza, Hepatitis A/B, Pneumococcal, etc.). VIS sheets for all vaccines are available through the CDC website: http://www.cdc.gov/vaccines/pubs/vis/default.htm.

- VIS sheets for distribution to patients are present on site. Site personnel should be able to verbalize standard practices regarding VIS distribution.
- The date the VIS was given and the publication date of the VIS MUST be documented in the patient's medical record. (See Attachments)
- The most current Vaccine Information Statements (VIS) are available from state and local health departments or can be downloaded from the CDC website at http://www.cdc.gov/vaccines/pubs/vis/default.htm or by calling the CDC Immunization Hotline at (800) 232-4636. (800-CDC-INFO).

C. Prescription Labeling:

- All stored and dispensed prescription drugs are appropriately labeled with the following:
  a. Provider's name
  b. Patient's name
  c. Drug name
  d. Dose
  e. Frequency
  f. Route
  g. Quantity dispensed
  h. Manufacturer's name and lot number

D. Pharmacy:

- If there is a pharmacy on site, it is licensed by the CA State Board of Pharmacy, with a licensed pharmacist monitoring drug distribution and current policies/procedures for drug storage and dispensing.

E. Drug Expiration:

- There are no expired drugs on site, as they may not be distributed or dispensed.
- The manufacturer's expiration date must appear on the label of all drugs. All prescription or over the counter (OTC) drugs not bearing the expiration date are deemed to have expired.
- Multi-dose vials (MDV): Per CDC, MDV injectable expire 28 days once opened unless manufacturer recommends a longer or shorter expiration date. Vials must be labeled with date opened. Unlabeled open vials are deemed to have expired.
- Site follows the procedures below to monitor for expiration date and a method of dispose of expired medications/hazardous substances (i.e., sample medications), vaccines, and infant formula. A tracking log is the preferred method of tracking expiration dates (see Attachments).

Frequency of monitoring:	Method of disposal:
☐ Monthly, ☐ Weekly, or ☐ Other:	Prescription & OTC drugs / hazardous substances / infant formula: Vaccines:

CONTROLLED SUBSTANCE LOG

Medication Name: _____

Provider's DEA number: _____

Dose (mg/ml – mg/tab): _____

Original Quantity (Original number of doses): _____

Date	Patient Name	Dispensed/Given By	Quantity Dispensed	Balance Available

For information on COVID-19 vaccine storage, see the COVID-19 Vaccine Addendum in CDC's *Vaccine Storage & Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling!

Do you see your clinic or practice making any of these frequently reported errors in vaccine storage and handling? Although some of these errors are much more serious than others, none of them should occur. Be sure your healthcare setting is not making any of these ***preventable*** *errors.*

ERROR: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines

- Everyone in the office should know the basics of vaccine handling, including what to do when a shipment arrives and what to do in the event of an equipment failure or power outage.
- Train at least one back-up person. The back-up and primary persons should be equally familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, what to do when an out-of-range temperature occurs, and how to appropriately respond to an equipment problem or power outage.

ERROR: Storing vaccine inappropriately

- Be sure all office staff (especially persons involved in receiving vaccine shipments) understand the importance of properly storing vaccines immediately after they arrive.
- Know which vaccines should be refrigerated and which should be frozen. Storage information is found in the package insert. For quick reference, post IAC's *Vaccine Handling Tips* (www.immunize.org/catg.d/p3048.pdf) on the refrigerator and freezer.
- Always store vaccines (and temperature monitoring devices) in the body of the refrigerator – not in the vegetable bins, on the floor, next to the walls, in the door, or near the cold air outlet from the freezer. The temperature in these areas may differ significantly from the temperature in the body of the unit.
- Don't over-pack the unit. Place the vaccine packages in such a way that air can circulate around the compartment.
- Always store vaccines in their original packaging.

ERROR: Using the wrong type of equipment

STORAGE UNITS

- CDC recommends storing vaccines in separate, self-contained units that only refrigerate or only freeze. If a combination refrigerator/freezer must be used, only refrigerated vaccines should be stored in the unit, and a separate stand-alone freezer should be used for frozen vaccines.
- Never store vaccines in a "dormitory-style" unit (i.e., a small refrigerator-freezer unit with one exterior door and a freezer compartment inside the refrigerator). These units cannot maintain stable temperatures.

TEMPERATURE MONITORING DEVICES/DIGITAL DATA LOGGERS

- Use only temperature monitoring devices (digital data loggers [DDL] preferred and required for VFC vaccine storage) for continuous temperature monitoring and recordings. Set the DDL to measure and record temperatures no less than every 30 minutes. Be sure the DDL has a current and valid Certificate of Calibration Testing (aka Report of Calibration).
- Buffer the DDL's temperature probe by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon® or aluminum). Use of a buffer ensures you are not just measuring air temperature, which is subject to fluctuation when you open the door.

For more detailed information, see the *Vaccine Storage and Temperature Monitoring Equipment* section of CDC's *Vaccine Storage & Handling Toolkit* (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).

ERROR: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals

- Unfortunately, too much vaccine is lost every year because storage unit doors were left open. Remind staff to *completely* close the door every time they open the refrigerator or freezer.
- Check the seals on the doors on a regular schedule, such as when you're taking inventory. If there is any indication the door seal may be cracked or not sealing properly, have it replaced. (This is much less costly than replacing a box of, for example, pneumococcal conjugate or varicella vaccine!)

CONTINUED ON THE NEXT PAGE ▶

immunization action coalition
IAC
immunize.org

Saint Paul, Minnesota ▪ 651-647-9009 ▪ www.immunize.org ▪ www.vaccineinformation.org

www.immunize.org/catg.d/p3036.pdf ▪ Item #P3036 (8/21)

ERROR: Storing food and drinks in the vaccine refrigerator

- Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines. Store only vaccines in the designated units.

ERROR: Inadvertently cutting the power supply to the storage units

- Be sure everyone in your office, including the janitorial staff, understands that very expensive and fragile vaccines are being stored in the refrigerator and freezer.
- Post a *Do Not Unplug* sign (www.immunize.org/catg.d/p2090.pdf) next to electrical outlets for the refrigerator and freezer, and a *Do Not Stop Power* warning label (www.immunize.org/catg.d/p2091.pdf) by the circuit breaker for the electrical outlets.

ERROR: Recording temperatures an insufficient number of times each day

- If using a temperature monitoring device (TMD) (digital data loggers [DDL] preferred and required for VFC vaccine storage) that records minimum/maximum (min/max) temperatures (i.e., this highest and lowest temperature during a specific time period), document min/max and current temperatures *once* each workday, preferably in the morning. If using a TMD that does not record min/max temperatures, document current temperatures *twice,* at the beginning and end of each workday.
- Record the temperatures you observed on an appropriate log. IAC has temperature logs (www.immunize.org/handouts/temperature-logs.asp) available in both Fahrenheit and Celsius formats.
- Record temperatures for ALL units being used to store vaccine. Don't forget to check temperatures for both the refrigerator and freezer.

ERROR: Documenting out-of-range temperatures on vaccine temperature logs but not taking action

- If you find out-of-range temperatures…do something! The viability of your vaccine – and the protection of your patients – is at stake.
- Guidance on what to do may be found on IAC's temperature logs (www.immunize.org/handouts/temperature-logs.asp) and Vaccine Storage Troubleshooting Record (www.immunize.org/catg.d/p3041.pdf).
- Have an Emergency Response Plan and trained staff in place before a problem occurs. For help in developing a plan, see the Checklist For Emergency Vaccine Storage, Handling, and Transport in the *Resources* section of CDC's *Vaccine Storage & Handling Toolkit* (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).

ERROR: Discarding temperature logs too soon

Keep your temperature logs for at least 3 years. Why?

- You can track recurring problems as the storage unit ages.
- If out-of-range temperatures have been documented, you can determine how long and how often this has been occurring.
- This can be a great way to demonstrate why you need a new refrigerator or freezer!

ERROR: Not using vaccine with the soonest expiration date first

When unloading a new shipment of vaccine:

- Move vaccine with the shortest expiration date to the front of the unit, making it easier for staff to access this vaccine first.
- Mark the "older" vaccine to be used first.

ERROR: Dealing inappropriately with expired vaccines

- Carefully monitor your usage to ensure viable vaccines don't expire! As discussed above, place vaccines with the shortest expiration dates at the front of the unit.
- If you discover expired vaccines, immediately remove them from the unit so that they are not inadvertently administered.

ERROR: Discarding multidose vials prematurely

- Almost all multidose vials (MDV) of vaccines contain a preservative and can be used until the expiration date on the vial, unless there is actual contamination or the vials are not stored under appropriate conditions. For some vaccines, the manufacturer may specify that once the MDV has been entered or the rubber stopper punctured, the vaccine must be used within a certain number of hours or days. For specific guidance, refer to the package insert (see www.immunize.org/fda).

Temperature Log for Refrigerator – Fahrenheit

DAYS 1–15

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the refrigerator's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 46°F) or too cold (below 36°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp in Unit (since previous reading)															
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
TEMPERATURES 46°F															
45°F															
44°F															
43°F															
42°F															
Aim for 41° 41°F															
ACCEPTABLE 40°F															
39°F															
38°F															
37°F															
36°F															
Danger! Temperatures below 36°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACTION Write any out-of-range temps (above 46°F or below 36°F) here:															
Room Temperature															

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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Adapted with appreciation from California Department of Public Health

www.immunize.org/catg.d/p3037F.pdf ▪ Item #P3037F (8/21)

Temperature Log for Refrigerator – Fahrenheit

DAYS 16–31

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the refrigerator's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 46°F) or too cold (below 36°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp in Unit (since previous reading)																
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES 46° F																
45° F																
44° F																
43° F																
42° F																
Aim for 41° 41° F																
ACCEPTABLE 40° F																
39° F																
38° F																
37° F																
36° F																
Danger! Temperatures below 36°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION Write any out-of-range temps (above 46°F or below 36°F) here:																
Room Temperature																

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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Adapted with appreciation from California Department of Public Health

www.immunize.org/catg.d/p3037F.pdf • Item #P3037F (8/21)

Temperature Log for Freezer – Fahrenheit

DAYS 1–15

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the freezer's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp in Unit (since previous reading)															
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACCEPTABLE TEMPERATURES **5°F**															
4°F															
3°F															
2°F															
1°F															
0°F															
-1°F															
-2°F															
-3°F															
-4°F															
-58°F to -5°F															
ACTION Write any out-of-range temps (above 5°F or below -58°F) here.															
Room Temperature															

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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www.immunize.org/catg.d/p3038F.pdf ▪ Item #P3038F (8/21)

Temperature Log for Freezer – Fahrenheit

DAYS 16–31

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the freezer's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp in Unit (since previous reading)	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES **5°F**																
4°F																
3°F																
2°F																
1°F																
0°F																
-1°F																
-2°F																
-3°F																
-4°F																
-58°F to -5°F																
ACTION Write any out-of-range temps (above 5°F or below -58°F) here.																
Room Temperature																

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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Adapted with appreciation from California Department of Public Health

www.immunize.org/catg.d/p3038F.pdf ▪ Item #P3038F (8/21)

Emergency Response Worksheet

What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Notify the local or state health department or call the manufacturer (see manufacturers' phone numbers below).
4. Record action taken.

Record this information*:

1. Temperature of refrigerator: current_____ max._____ min._____
2. Temperature of freezer: current_____ max._____ min._____
3. Air temperature of room where refrigerator is located:_____
4. Estimated amount of time the unit's temperature was outside normal range:
   refrigerator _____ freezer _____
5. Vaccines in the refrigerator/freezer during the event (use the table below)

* Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Vaccines Stored in Freezer

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Other Conditions

1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Y N
3. Other: _____
   _____
   _____

Manufacturers

Crucell Vaccines Inc.	(800) 533-5899
CSL Biotherapies, Inc.	(888) 435-8633
GlaxoSmithKline	(888) 825-5249
MedImmune, Inc.	(877) 633-4411
Merck & Co., Inc.	(800) 672-6372
Novartis Vaccines	(800) 244-7668
Pfizer Inc.	(800) 438-1985
sanofi pasteur	(800) 822-2463

Other Resources

Local health department phone number _____ State health department phone number _____

Adapted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010.

www.immunize.org/catg.d/p3051.pdf • Item #P3051 (10/10)

Vaccine Storage Power Outage / Disaster Recovery Plan

*** All VFC Providers are required to complete this document ***

Clinic Name:	**County:**
Person Completing Form:	**Date:**

If you have any questions about vaccine transportation or stability call: [1-877-243-8832] (CA Vaccines for Children Program)

In advance of an emergency power outage, providers should:

1. Identify and have an agreement with an alternative storage facility that has refrigerated storage that meets VFC criteria (i.e.: hospital, health department, fire department, etc.) with backup power (generator) where the refrigerated vaccine can be properly stored and monitored for the interim.
2. Insure the availability of staff to pack and transport the vaccine.
3. Maintain the appropriate packing materials (coolers, gel packs, dry ice for Varicella, etc.)
4. Insure a means of transport for the vaccine to the secure storage facility.

NOTE: Whenever possible, providers should anticipate the possibility of a power disruption and suspend vaccine activities **before** the onset of emergency conditions to allow sufficient time for packing and transporting vaccine.

Emergency Procedures

A. List emergency phone numbers, alternate storage facilities, and points of contact for:

Designated person(s) shall be responsible for:

- Monitoring the operation of the vaccine storage equipment and systems daily.
- Tracking inclement weather conditions. Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create a shutdown in power. An alarm/notification system is recommended for practices with an inventory of $5,000 or more.
- Assuring the appropriate handling of the vaccine during the disaster or power outage.

Name of Employee	Title of Employee	Work Phone	Home Phone
Primary			
Backup			

Determine if your refrigerator is having a mechanical failure (no lights in the refrigerator, no fan noise, etc.) or if the building has lost electrical power. Check with the building maintenance to ensure that the generator is operational and has been activated. If a timeframe for the restoration cannot be determined, implement the following procedures.

Alternate Facility	Point of Contact	Work Phone	Emergency Phone

C. **Entering Vaccine Storage Facility:**

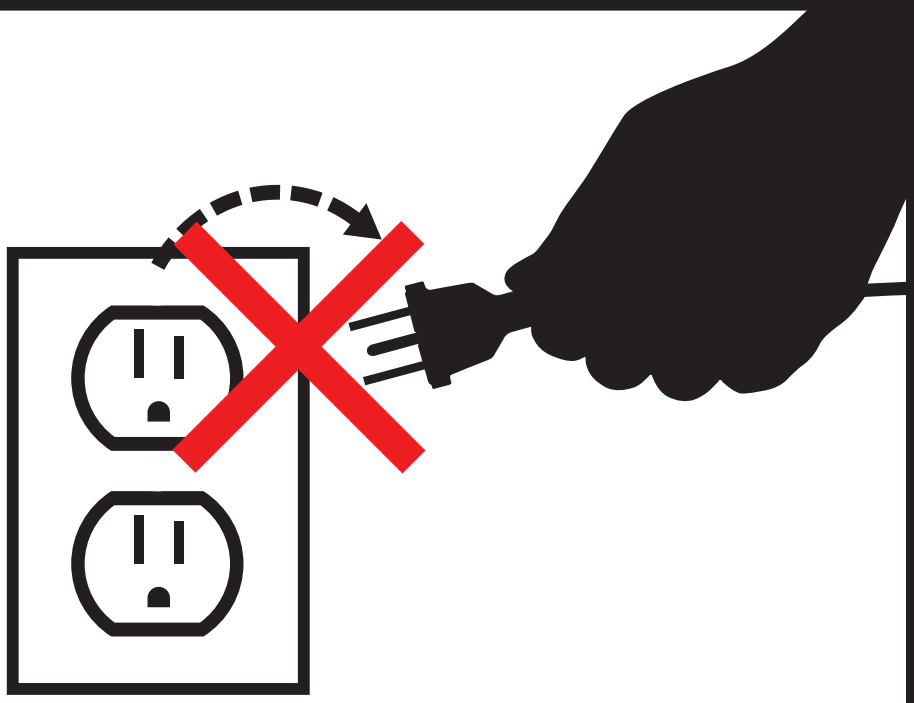
Describe how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a floor diagram and the locations of:

Item	**Location**
Doors	
Flashlights	
Spare Batteries	
Light Switches	
Keys	
Locks	
Alarms	
Circuit Breakers	
Packing Materials	

D. Conduct an inventory before you transport the vaccine.

E. Package the vaccine in a well-insulated container with ice packs.
Unpackaged vials of DTaP, IPV, Hib, Hep A, Hep *A/B,* Influenza, PCV7, PPV23, etc., must not directly touch cold packs as the vaccine may be inactivated. It is best to keep vaccines in their original package during transport. MMR is the exception and may be transported directly on cold packs. Remember that Varicella and MMRV must be kept frozen therefore package Varicella and MMRV separately from the other vaccines. Do not expose the other vaccines (except MMR) to freezing temperatures.

F. Move vaccines to back up storage according to pre-arranged plans.
- How to load transportation vehicle
- Routes to take (alternative routes if necessary)
- Time in route.



DO NOT UNPLUG REFRIGERATOR OR FREEZER!

¡No desconecte el refrigerador o congelador!

EXPENSIVE VACCINE IN STORAGE!

¡AVISO! CONTIENE VACUNAS CARAS.

In the event of a problem, immediately contact

Si hay un problema, comuníquese inmediatamente con

.....

Immunization Action Coalition St. Paul, Minnesota ▪ 651-647-9009 ▪ www.vaccineinformation.org ▪ www.immunize.org

www.immunize.org/catg.d/p2090.pdf ▪ Item #P2090 (10/15)

DO NOT UNPLUG REFRIGERATOR OR FREEZER!

¡No desconecte el refrigerador o congelador!

EXPENSIVE VACCINE IN STORAGE!

¡AVISO! CONTIENE VACUNAS CARAS.

In the event of a problem, immediately contact

Si hay un problema, comuníquese inmediatamente con

.....

MONTHLY VERIFICATION LOG

YEAR: _____

Month	Date	Medication in Refrig/ Freezer	Locked Meds and/or Controlled Meds	Sample Medications	Emergency Kit (Equipment and Meds)	Oxygen level (at least ¾ full), Mask, Cannula, and tubing	Laboratory (reagents, hemoccult etc.)	Laboratory (vacutainer tubes, culture medium, collection systems, etc)	Other
January									
February									
March									
April									
May									
June									
July									
August									
September									
October									
November									
December									

Instructions:

* Initial each category as you check the items
* An Initial indicates that the items have been checked; expired medications and supplies purged, and properly disposed of.

_____ _____

Initial Print name of person checking

_____ _____

Initial Print name of person checking

POLICY AND PROCEDURE Vaccine Information Statements (VISs)

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC). VISs explain both the benefits and risks of a vaccine to adult vaccine recipients and the parents or legal representatives of vaccines who are children and adolescents. Federal law requires that VISs be handed out whenever certain vaccinations are given (before each dose).

Copies are available in English and many other languages from CDC's website at www.cdc.gov/vaccines/pubs/vis.

Purpose: To educate adult patients or parents/guardians about the benefits and risks of any vaccinations(s) recommended for them.

Procedure: Provide a Vaccine Information Statement (VIS) when a vaccination is given. As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer, to any child or adult, any of the following vaccines – diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) – shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative* of any child to whom the provider intends to administer such vaccine,

or

- to any adult† to whom the provider intends to administer such vaccine.

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

VISs should be supplemented with visual presentations or oral explanations as appropriate.

*"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

†In the case of an incompetent adult, relevant VISs shall be provided to the individual's legal representative. If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each vaccination.

Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided, indicating:

(1) the edition date of the Vaccine Information Statement distributed, and
(2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log):

(3) the name, address and title of the individual who administers the vaccine,
(4) the date of administration, and
(5) the vaccine manufacturer and lot number of the vaccine used.

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC). VISs explain both the benefits and risks of a vaccine to adult vaccine recipients and the parents or legal representatives of vaccinees who are children and adolescents.

Federal law requires that VISs be handed out whenever certain vaccinations are given (before each dose).

Out-of-date translations

The translations for some VISs on our website are from previously published English-language versions that have since been updated. Unfortunately, IAC is not always able to obtain translations as updates are issued. Please ensure that your patients receive information consistent with the current **English-language version** of the following VISs.

You Must Provide Patients with Vaccine Information Statements (VISs) – It's Federal Law!

What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vaccinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act) requires a healthcare professional to provide a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox).

Where to get VISs

All available VISs can be downloaded from the websites of Immunize.org at www.immunize.org/vis or CDC at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

Translations: You can find VISs in more than 40 languages on the Immunize.org website at www.immunize.org/vis.

To obtain translations of VIS in languages other than English, go to www.immunize.org/vis.

According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private healthcare setting.

Top 10 Facts About VISs

FACT 1 It's federal law! You must provide current* VISs to all your patients before vaccinating them.

Federal law requires that VISs must be used for patients of **ALL ages** when administering these vaccines:

- DTaP (includes DT)
- Td and Tdap
- hepatitis A
- hepatitis B
- Hib
- HPV
- influenza (inactivated and live, intranasal)
- MMR and MMRV
- meningococcal (MenACWY, MenB)
- pneumococcal conjugate
- polio
- rotavirus
- varicella (chickenpox)

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, dengue, ebola, Japanese encephalitis, pneumococcal polysaccharide, rabies, smallpox/monkeypox, typhoid, yellow fever, and zoster), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given.

*Federal law allows up to 6 months for a new VIS to be used.

FACT 2 VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format used, the goal is to provide a current VIS just prior to vaccination.

CONTINUED ON NEXT PAGE ▶

Most current versions of VISs (table)

As of June 30, 2022, the most recent versions of the VISs are as follows:

Adenovirus	1/8/20
Anthrax	1/8/20
Cholera	10/30/19
Dengue	12/17/21
DTaP	8/6/21
Ebola	6/30/22
Hepatitis A	10/15/21
Hepatitis B	10/15/21
Hib	8/6/21
HPV	8/6/21
Influenza	8/6/21
Japanese enceph	8/15/19
MenACWY	8/6/21
MenB	8/6/21
MMR	8/6/21
MMRV	8/6/21
Multi-vaccine	10/15/21
PCV	2/4/22
PPSV23	10/30/19
Polio	8/6/21
Rabies	6/2/22
Rotavirus	10/15/21
Smallpox/monkeypox	6/1/22
Td	8/6/21
Tdap	8/6/21
Typhoid	10/30/19
Varicella	8/6/21
Yellow fever	4/1/20
Zoster	2/4/22

A handy list of current VIS dates is also available at www.immunize.org/catg.d/p2029.pdf.

(For information on special circumstances involving vaccination of a child when a parent/legal representative is not available at the time of vaccination, see CDC's *VIS Frequently Asked Questions* at www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.)

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.

FACT 3 VISs are required in both public and private sector healthcare settings.

Federal law requires the use of VISs in both public and private sector settings, regardless of the source of payment for the vaccine.

FACT 4 You must provide a current VIS *before* a vaccine is administered to the patient.

A VIS provides information about the disease and the vaccine and must be given to the patient **before** a vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide a current VIS right before administering vaccines.

FACT 5 You must provide a current VIS for *each* dose of vaccine you administer.

The most current VIS must be provided before **each dose** of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

FACT 6 You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS.

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.

FACT 7 VISs should be given in a language/format that the recipient can understand, whenever possible.

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. To obtain VISs in more than 40 languages, visit the Immunize.org website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or oral explanations as needed.

FACT 8 Federal law does not require signed consent in order for a person to be vaccinated.

Signed consent is not required by federal law for vaccination (although some states may require it).

FACT 9 To verify that a VIS was given, providers must record in the patient's medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered)

In addition, providers must record:

- The office address and name and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number

FACT 10 VISs should not be altered before giving them to patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice's name, address, and contact information to an existing VIS.

Additional resources on VISs and their use are available from the following organizations:

Immunization Action Coalition

- *VIS general information and translations in more than 40 languages:* www.immunize.org/vis
- *Current Dates of Vaccine Information Statements:* www.immunize.org/catg.d/p2029.pdf

Centers for Disease Control and Prevention

- *VIS website:* www.cdc.gov/vaccines/hcp/vis
- *VIS Facts:* www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
- *VIS FAQs:* www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html

Frequently Asked Questions (FAQ) about Immunization Registries (Health Care Providers)

What is an immunization registry? What is CAIR?
An immunization registry is a secure web-based database that can store your patients' immunization records. A registry helps medical practices keep their patients vaccinated on time, avoiding under- or overimmunization. All 50 states have immunization registries. Our California Immunization Registry is also known as CAIR. California has 10 regional CAIR affiliates that cover the state. CAIR users pay nothing for software, training and help desk support.

Who can use CAIR?
CAIR can only be used by authorized medical office staff, hospitals, and public health departments for the purposes of evaluating shot records, sending reminders, billing, and protecting the public health. Programs such as WIC, child care, schools, foster care, and CalWORKS may also be authorized to view shot histories for the children they serve.

What can CAIR do for my practice? Will it increase my staff's busy workload?
CAIR reduces the staff time needed to:

- search for or replace patient immunization records
- provide records ("yellow cards" and "blue cards,") for school, camp, or other activities
- forecast which vaccines are due
- give "just-in-case" immunizations when earlier shot records are missing
- request shot records from other providers
- prepare reminder notices, and
- track vaccine inventory–including separate tracking for VFC vaccine supplies.

Immunization registry software works quickly and efficiently in a variety of clinic settings. The software has a high satisfaction rate. **Testimonials from medical office staff** affirm these advantages. Your regional CAIR representative can help assess your office workflow to maximize CAIR benefits for your practice.

What if our immunization rates are high already, should my practice join the registry?
CAIR:

- saves staff time and helps your patients
- consolidates records when children have been immunized by different providers.
- keeps children up-to-date by making rapid, accurate assessments of the increasingly complex vaccine schedule.
- accurately tracks your practice's coverage rates.
- improves immunization rates, whether high or low.

What computer equipment is needed?
Most computers with high-speed Internet access are adequate for registry use. Ask the CAIR Help Desk to help you evaluate your current system technology, identify any gaps.

Who will train our staff to use the registry?
CAIR training is available online. In some areas of the state, CAIR representatives can schedule free in-person training for your staff. **CAIR software is very user-friendly,** requiring no prior computer skills. Free Help Desk services are available to answer questions during normal business hours. Call 800-578-7889.

How do we ensure data accuracy?
CAIR software has built-in quality assurance features. Validation procedures identify inaccurate or missing data entered into the registry. The CAIR Help Desk can help you correct data.

How does CAIR integrate with your existing EMR/EHRs?

CAIR is currently able to receive immunization data from EMR/EHRs in HL7 format. Only HL7 data submission qualifies under the **EHR Incentive Program**. Data exchange file specifications are available on the **5 Steps to Data Exchange** page or from the CAIR Data Exchange staff at CAIRDataExchange@cdph.ca.gov. Providers interested in data exchange with CAIR should view the **5 Steps to Data Exchange** page to receive general instructions on the data submission process then register at the **CDPH Gateway/CAIR IZ Portal**

Are patients' records in CAIR kept secure?
CAIR complies with HIPAA and state law to protect patient privacy. Providers and CAIR staff must abide by confidentiality agreements in order to share patient records. Each viewing of patient records is tracked to maintain an "audit trail." Moreover, CAIR software has security features to protect confidential data from being seen by unauthorized sources.

Some families might not like the idea of a registry. What are their options?
Families have the choice of whether their children's records are shared with other CAIR users. **All parents or guardians must be notified** before their children's records are entered into CAIR. In practice, few families have chosen to not participate after this notification. Participating families also have the choice whether to receive reminders and to inspect their children's registry records for accuracy.

Can I access patient records from another part of California?
Yes. While the CAIR system currently has three distinct regional registries that are not connected (**CAIR regions)**, the CAIR Help Desk can assist providers to obtain patient records outside of their region. In 2019, data sharing among the CAIR registries will begin and participating providers will have access to patient immunization data from anywhere in the state.

How do we maintain control of our patients' records? Will other practices be able lure away our patients?
Your patients' immunization records are protected by security measures as well as by agreements signed by all providers participating in CAIR. Providers must use specific identifying information to search for children in the registry and cannot browse through all records.

Where can I learn more about CAIR?
Visit cairweb.org or contact the CAIR Help Desk at 800-578-7889 or your Local CAIR Representative.

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Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate

When is a CLIA Certificate Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

DO I NEED TO HAVE A CLIA CERTIFICATE?

CLIA requires all facilities that perform even one test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

WHAT ARE THE DIFFERENT TYPES OF CLIA CERTIFICATES AND HOW LONG ARE THEY EFFECTIVE?

All types of certificates are effective for two years and the different types of certificates are:

- **Certificate of Waiver (COW):**
  Issued to a laboratory that performs only waived tests.
- **Certificate for Provider Performed Microscopy (PPM) procedures:**
  Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.
- **Certificate of Registration:**
  Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- **Certificate of Compliance (COC):**
  Issued to a laboratory once the State Department of Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

- **Certificate of Accreditation (COA):**
  Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

There are six CMS-approved accreditation organizations:

- AABB
- American Osteopathic Association (AOA)
- American Society of Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Contact information for the above CMS-approved accreditation organizations is available on the CMS CLIA web site at www.cms.hhs.gov/clia. If you apply for accreditation by one of the CMS-approved accreditation organizations, you must also apply to CMS for a COA concurrently.

WHAT IS A WAIVED TEST?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result". The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

HOW CAN I FIND A LIST OF WAIVED TESTS?

For a list of waived tests sorted by analyte name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm.

WHERE CAN I FIND INFORMATION ABOUT TESTS CATEGORIZED AS NONWAIVED (I.E., MODERATE AND/OR HIGH COMPLEXITY)?

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity), refer to the lists of tests online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

You may also contact the local survey agency at your State Health Department for categorization information concerning tests that you may be performing in your laboratory. A list of State Agency addresses, phone numbers and contact persons is available online under the heading State Survey Agencies (CLIA Contact List) at the CMS CLIA website. If you do not have online access or have questions concerning certification, you may contact the CMS CLIA Central Office at 410-786-3531 for the address and phone number of your local State Agency.

HOW DO I APPLY FOR A CLIA CERTIFICATE?

The CLIA application (Form CMS-116) is available online at the CMS CLIA website located at the end of this brochure. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located. This information is available online or you may contact the CMS CLIA Central Office.

IS THERE ANY TYPE OF LABORATORY TESTING THAT IS NOT SUBJECT TO A CLIA CERTIFICATE?

Yes, there are some testing exceptions that do not require CLIA certification.

The following **exceptions to CLIA certification** apply regardless of a laboratory's location:

- Any laboratory that only performs testing for forensic purposes;
- Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients; or

- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

ARE THERE ANY STATES THAT EXEMPT ME FROM HAVING TO APPLY FOR A CLIA CERTIFICATE?

Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the New York State Agency concerning your need for a CLIA certificate.

IF I HAVE MORE THAN ONE LABORATORY LOCATION, DO I NEED A CLIA CERTIFICATE FOR EACH LOCATION?

You will need a CLIA certificate for **each** location where you perform testing **unless** you qualify for one of the exceptions listed below.

- 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.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing, may file a single application.
- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Contact your State Agency if you have questions or you are filing a single application for more than one testing site.

WHAT KIND OF FEES DO I HAVE TO PAY TO CMS FOR A CLIA CERTIFICATE?

If you apply for COW or a PPM certificate, you will pay a minimal certificate fee every two years. There are no registration or compliance fees.

If you apply for a COC, you will pay a one time minimal registration fee that covers the cost of the CLIA enrollment in addition to a compliance fee that covers the cost of the initial inspection by the State Agency. CMS will send you a Certificate of Registration. Once compliance has been determined by your inspection, you will pay a certificate fee to CMS and CMS will send you a COC. A two-year certificate cycle is then established, and you will pay a certificate fee and a compliance fee every two years. CMS will send you a COC as long as your laboratory is in compliance.

If you apply for a COA, you will pay a minimal registration fee that covers the cost of the CLIA enrollment. Once CMS receives verification from the accreditation organization that you have selected, you will pay a certificate fee and validation fee to CMS and CMS will send you a COA. A two year certificate cycle is then established and you will pay a certificate fee and a validation fee every two years. CMS will send you a COA as long as your laboratory remains compliant. You will pay survey and any other fees to the accreditation organization.

You can obtain more information concerning the amount of certificate fees from the CMS CLIA website under "CLIA Certificate Fee Schedule" or from your State Agency. For information concerning compliance (survey) fees, you may contact your State Agency or accreditation organization. These fees are based on the number and types of testing you perform and must cover the cost of the CLIA program because CLIA is entirely user fee funded.

WILL I RECEIVE AN IDENTIFYING CLIA NUMBER?

You will receive a ten-digit number on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

WHEN CAN I BEGIN TESTING?

After you apply for your certificate, you will receive a coupon notifying you of the corresponding fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate containing your CLIA number. However, you need to check with your State Agency since some states have additional requirements.

WILL MY LABORATORY RECEIVE A CMS SURVEY?

Laboratories that have a COW or PPM certificate are not subject to routine surveys. However, CMS is currently conducting a project whereby a small percentage of laboratories that perform only waived testing may receive an educational visit. These visits provide helpful information to staff to help assure the quality of testing and have been extremely well received.

If your laboratory performs any nonwaived testing, the laboratory may have either a COC or COA. All laboratories with either of these certificate types must meet all nonwaived testing requirements and are subject to biennial surveys, by CMS or a CMS agent (such as a surveyor from the State Agency) or by a CMS-approved accreditation organization, if the laboratory is accredited. COA laboratories must also meet the requirements of their accreditation organization.

Additionally, a limited percentage of laboratories with a COA will receive a validation survey by CMS or a CMS agent. This is a survey performed by CMS or a CMS agent to evaluate the results of the most recent survey performed by an accreditation organization.

NOTE: If CMS or the State Agency receives a complaint against your laboratory, you may receive an unannounced on site survey, even though you only perform waived tests or PPM procedures.

IF I HAVE A CERTIFICATE FOR PPM PROCEDURES, A CERTIFICATE OF REGISTRATION, A COA OR A COC, CAN I ALSO PERFORM WAIVED TESTS?

Yes, these certificates permit laboratories to also perform waived tests.

IF I HAVE A COA OR A COC, CAN I ALSO PERFORM PPM PROCEDURES?

Yes, these certificates permit laboratories to perform PPM procedures as well as waived tests. The certificate you obtain should be for the highest (most complex) category of testing you perform.

DO I NEED TO NOTIFY ANYONE IF I MAKE ANY CHANGES IN MY LABORATORY?

For **all** types of CLIA certification, you must notify the State Agency or your accreditation organization within 30 days of any changes in:

- Ownership
- Name
- Location
- Director
- Technical supervisor (for high complexity testing only)

If you perform only waived tests and wish to add PPM procedures or other nonwaived (moderate or high complexity) testing to your menu, you must reapply for the appropriate certificate using the same form (Form CMS-116) you used for your initial CLIA certification. However, you cannot begin nonwaived testing until you have paid the appropriate fee, and have received the appropriate certificate.

If you perform PPM procedures and wish to add other nonwaived (moderate or high complexity) testing, you must first apply for the appropriate certificate.

If you have a COC or COA and wish to add tests categorized under a different laboratory specialty or subspecialty than those on your current certificate or that employ a different test method from those you are already performing, you must notify the State Agency or the accreditation organization of the new testing.

IF I HAVE ANY QUESTIONS ABOUT MY CERTIFICATE OR CHANGES IN MY TEST MENU, WHO SHOULD I CONTACT?

You should contact the State Agency where your laboratory is located. You can find this information as well as other information about CLIA at www.cms.hhs.gov/clia or you may contact the CMS CLIA Central Office at 410-786-3531.

WHERE CAN I FIND ADDITIONAL INFORMATION AND GUIDANCE?

Refer to the "The State Operations Manual", Appendix C – Interpretive Guidelines (CMS Publication 7) available on the CMS website at: www.cms.hhs.gov/clia.

Links to other laboratory-related resources can be found at these websites:

CDC: www.phppo.cdc.gov/clia/default.asp
FDA: www.fda.gov/cdrh/CLIA/index.html

SECTION	Approval date:	
Clinical Services	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Laboratory Services	Revision date:	

POLICY:

The site will operate in compliance with Clinical Laboratory Improvement Amendment (CLIA) regulations. Therefore, the site shall meet all quality standards to ensure accuracy, reliability, and timeliness of patient test results. All lab results are to be communicated to the provider and member in a timely manner.

PROCEDURE:

I. Laboratory test procedures are performed according to current site-specific CLIA certificate:
   A. All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease, have a current, unrevoked, unsuspended site-specific CLIA certificate, or evidence of renewal.
      The CLIA certificate on site includes one of the following:
      a. Certificate of Waiver: Site is able to perform only exempt waived tests so, therefore, has a current CLIA Certificate of Waiver. The current listing of waived tests may be obtained at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm
         - There are no specific CLIA regulations regarding the performance of waived tests. Therefore, site personnel are expected to follow the manufacturer's instructions.
         - Laboratories with Certificates of Waiver may not be routinely inspected by DHS Laboratory Field Services Division, but may be inspected as part of complaint investigations and/or on a random basis to determine whether only waived tests are being performed.
      b. Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists or mid-level practitioners are able to perform PPM procedures and waived tests.
      c. Certificate of Registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations is determined by survey.
         - For moderate and/or high complexity lab testing, the CLIA regulations list specific requirements for laboratory proficiency testing, patient test management, quality control, quality assurance, personnel and inspections.
      d. Certificate of Compliance: Lab has been surveyed and found to be in compliance with all applicable CLIA requirements.
      e. Certificate of Accreditation: Lab is accredited by an accreditation organization approved by the Centers of Medicare & Medicaid Services (CMS).

   B. CLIA certification/re-certification includes an evaluation every two years (or sooner, if complaint driven) by DHS of personnel licenses/training, laboratory site inspection and demonstration of testing proficiency of moderate and high-complexity test sites.

II. Testing personnel performing clinical lab procedures have been trained.
   A. Prior to testing biological specimens, personnel are 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.
   B. Site personnel that perform CLIA waived tests have access to and are able to follow test manufacturer's instructions.
   C. When requested, site personnel are able to provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.
   D. The required training and certification are established by legislation (CA B&P Codes, §1200-1213) for personnel performing moderate and high complexity tests. Reviewers are not expected to complete an in-depth evaluation of personnel performing moderate and high complexity tests.

III. Lab Supplies are inaccessible to unauthorized persons.

IV. Lab test supplies (e.g., vacutainers, culture swabs, test solutions) shall not be expired. Site follows the procedures below to monitoring for expiration date and a method of dispose of expired lab test supplies. A tracking log is the preferred method of tracking expiration dates (see Attachment).

Frequency of monitoring:	Method of disposal:
☐ Monthly, ☐ Weekly, or ☐ Other:	Describe:

V. The provider will review, initial, and date the original copy of each laboratory report, which is then filed in the member's medical record.

NOTE: For questions regarding CLIA certification, laboratory licensing, and personnel, call CA Department of Public Health Laboratory Field Services at (510) 620-3800.

SECTION	Approval date:	
Clinical Services	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Radiology Services	Revision date:	

POLICY:

The site shall meet California Department of Public Health (CDPH) Radiological Health Branch inspection and safety regulations by ensuring that radiation is used safely and effectively, individuals are protected from unnecessary radiation is used safely and effectively, individuals are protected from unnecessary radiation exposure and that environmental quality is preserved and maintained (17 CCR §30255, §30305, §30404, §30405). The Radiologic Health Branch of the Food, Drug, and Radiation Safety Division of the 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.

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.

PROCEDURE:

I. Site has current CA Radiologic Health Branch (RHB) Inspection Report and Proof of Registration (receipt of payment or cancelled check) issued by the RHB for any radiological equipment on site.

   A. The site shall have current documentation of one of the following:
      - Inspection Report and Proof of Registration, or
      - Inspection Report and Proof of Registration and Short Form Sign-off sheet, or
      - Inspection Report, Proof of Registration and Notice of Violation form and approval letter for corrective action plan from the CA RHB.

   B. Equipment inspection, based on a “priority” rating system, is established by legislation (CA H&S Code, Section 115115)
      - Mammography equipment is inspected annually (Mammography federal FDA Certification on site and CA Mammography X-ray Equipment and Facility Accreditation Certification posted on the machine.
      - 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 use, and likelihood of radiation exposure
      - Site personnel shall contact the Radiological Health Branch at (916) 327-5106 for more information on the “current” status of equipment inspection.

II. The following documents shall be posted on site:

A. Current copy of Title 17 with a posted notice about availability of Title 17 and its location.
B. “Radiation Safety Operating Procedures” posted in a highly visible location.
C. “Notice to Employees Poster” posted in a highly visible location.
D. “Caution, X-ray” sign posted on or next to door of each room that has X-ray equipment
E. Physician Supervision/Operator certificate posted and within current expiration date
F. Technologist certificate shall be maintained current posted on site
    - If there are a large number of 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” limits the technician to one of the 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.

III. The following radiological protective equipment shall be present on site, unless only dexascanners are present:

A. Operator protection devices: radiologic equipment operator shall use lead apron or lead shield
B. Gonadal shield (0.5 mm or greater lead equivalent): for patient procedures in which gonads are in direct beam

NOTE:

For questions regarding radiologic safety (e.g., expired or missing inspection documentation on site), call CDPH Radiological Health Branch (Compliance Unit) at (916) 327-5106. For Radiation Emergency Assistance, call 1-800-852-7550.

SECTION	Approval date:	
Preventive Services	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Preventive Care Screening Equipment	**Revision date:**	

POLICY:

Preventive health care services and health appraisal examinations are provided on a periodic basis for detection of asymptomatic diseases. Examination equipment, appropriate for primary care services is required to be available at the Primary Care Physician office site.

PROCEDURE:

I. The following equipment shall be maintained on site and will be appropriate to the population served.

A. Examination table:
- The examination table has a protective barrier to cover the exam table surface that is changed between patients contact. The exam table is in "good repair" (i.e., is clean, well maintained, and in proper working order).

B. Scales:
- Infant scales are marked and accurate to increments of one (1) ounce or less, and have a capacity of at least 35 pounds. Infants and children are weighed undressed or wearing indoor minimal clothing. If the child resists to the extent that s/he cannot be weighed accurately, document in the medical record that the child resisted and the weight measurement is imprecise.
- Standing floor scales are marked and are accurate to increments of one-forth (¼) pound or less with a capacity of at least 300.
- Balance beam or electronic scales are appropriate for clinic use.
- Electronic or digital scales have automatic zeroing and lock-in weight features.
- Spring balance scales (e.g., bathroom scales) are UNSATISFACTORY for clinical use.

C. Measuring stature devices: (includes length, height, and head circumference)
- Rigid 90º right angle headboard block that is perpendicular to the recumbent measurement surface or vertical to the wall mounted standing measurement surface.
- Flat, paper or plastic, non-stretchable tape or yardstick marked to one-eighth inch (1/8 or 1mm) or less. The "0" of the tape is exactly as the base of the headboard for recumbent measurement, or exactly at foot level for standing measurement.
- Non-flexible footboard at 90º right angle perpendicular to the recumbent measurement surface or flat floor surfaces for standing. Adult scale height measuring devices are unacceptable.
- Head circumference measurement uses a non-stretchable tape measuring device marked to (1/8 or 1mm) or less (up to 24 months of age)

D. Basic exam equipment available for use in exam rooms:
- Thermometers: oral and/or tympanic
- Stethoscope and sphygmomanometer with various sized cuffs (e.g., small, regular, extra large/obese/thigh)
- Percussion hammer
- Tongue blades
- Patient gowns are appropriate to the population served on site
- Ophthalmoscope
- Otoscope with adult and pediatric ear speculums

E. Vision testing:
- Members who are 3 to 20 years old and are seen for pediatric preventive services shall have a visual acuity screening using eye charts recommended by the American Academy of Pediatrics (AAP). Both literate (e.g., Sloan or Snellen) and illiterate (e.g., HOTV or LEA) eye charts are available.
- Wall mounted eye charts are height adjustable and positioned at the eye-level of the patient.
- Heel lines are clearly established and aligned with the center of the eye chart at a distance of 10 or 20 feet depending on the 10-foot or 20-foot vision chart used. 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.
- Eye charts are located in an area with adequate lighting and at height appropriate to patient (adjustable).
- Effective occlusion, such as with tape or an occlusive patch of the eye not being tested, is important to eliminate the possibility of peeking. If patch is not available or tolerated, acceptable occluders include specially designed occlusion glasses and for children 10 years and older, an occlusive paddle with a hole for the child to look through.
- For infection control purposes, disposable occlusive devices are preferred because they minimize the risk of transmitting infection between patients.

Please visit the AAP link for more detailed requirements:
https://pediatrics.aappublications.org/content/137/1/e20153597

F. Audiometric Testing:
- Members who are 4 to 20 years old and are seen for pediatric preventive services shall have an audiometric screening with a pure tone, air conduction audiometer available. Members that are referred to another provider for audiometric testing shall have a copy of their test results/report available in the member's medical record for review.
- The pure tone audiometer shall have the minimum ability to:
  a. Produce intensities between 0 to 80 dB;
  b. Have a headset with right and left earphones;
  c. Be operated manually; and
  d. Produce frequencies at 1000, 2000, 3000, 4000, 6000, and 8000 Hz.

Please visit the following links for more detailed requirements:
https://pediatriccare.solutions.aap.org/DocumentLibrary/periodicity_schedule.pdf
https://www.sciencedirect.com/science/article/abs/pii/S1054139X16000483

SECTION	Approval date:	
Preventive Services	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Health Education	Revision date:	

POLICY:

Health education services and Plan-specific resource information are available to Plan members.

PROCEDURE:

I. Health education materials will be maintained on site or made available upon request.
   A. Providers and/or staff will provide health education materials and/or resources to members as appropriate.

   B. Providers and/or staff providing verbal health education, educational materials, Plan-specific resources and/or referrals to classes will document titles/content in the patient's medical record.

II. Educational materials maintained on site will be applicable to the practice and the population served.

III. Educational materials will be available in threshold languages identified for county and/or area of site location.

Dear Valued Customer,

Thank you for your interest in CIDEX® Solutions. Regarding your questions on disposal in California let me provide you with the following information:

SB 2035 was enrolled on the 8th of September 2000. This law went into effect January 1, 2001 and states that: ***'Treatment does not include the combination of glutaraldehyde or ortho-phthalaldehyde, which is used by medical facilities to disinfect medical devices, with formulations containing glycine as the sole active chemical, if the process is carried out onsite."***

What this means:
Customers using Glutaraldehyde solutions or CIDEX® OPA Solution can treat the solution with Glycine prior to disposal WITHOUT a treatment permit from the State.

To treat one gallon of CIDEX® OPA Solution, add 25 grams of Glycine and wait 1 hour prior to disposal.

To treat one gallon of CIDEX® Activated Dialdehyde Solution or CIDEXPLUS® Solution, add 25 grams of Glycine and wait 5 minutes prior to disposal.

Thank you for contacting Advanced Sterilization Products. If you should have additional questions, please call ASP Professional Services at (888)-783-7723.

Sincerely,

33 Technology Drive, Irvine, CA 92618 · Tel: 949.581.5799 · Fax: 949.581.5997
ADVANCED STERILIZATION PRODUCTS
Division of Ethicon, Inc.
a Johnson & Johnson company

Warming CIDEX® Solutions

May 18, 2011

Dear Valued Customer,

Advanced Sterilization Products (ASP) occasionally receives questions from customers related to the reprocessing temperature of CIDEX® Solutions. All CIDEX® Solutions including CIDEX® OPA, CIDEXPLUS® 28 Day Solution and CIDEX® Activated Dialdehyde must be used in accordance with their respective Instructions for Use (IFU), and these IFUs indicate a minimum temperature requirement for high-level disinfection. Whether reprocessing devices manually in a basin or reprocessing using a legally marketed Automatic Endoscope Reprocessor, the temperature of the disinfectant solution must meet or exceed the minimum requirement listed in the solution's IFU.

ASP is aware that regulatory and accrediting organizations have increased their scrutiny of CIDEX® Solution temperatures, and often now request objective evidence that reprocessing temperatures meet requirements. In many cases, the ambient temperature of a reprocessing area is sufficient to ensure the minimum reprocessing temperature is maintained during disinfection. In some cases, however, a reprocessing area may not be sufficiently warm to ensure a basin of CIDEX® Solution is above the required temperature, and in this case the CIDEX® Solution **should not be used** until the temperature is sufficient. Customers must make certain that the solution is warmed to the appropriate temperature before the reprocessing begins, and should have reasonable confidence that the minimum temperature is maintained or exceeded throughout the soaking time.

While ensuring the disinfectant solution temperature meets the minimum requirements is essential, ASP does not endorse any particular system to warm CIDEX® Solutions should they not meet the temperature requirement. ASP strongly recommends that our customers develop and discuss their internal practices for heating disinfectant solutions in cooperation with their Industrial Hygiene, Facilities and risk management personnel. Should a warmer be used with CIDEX® Solutions, heat only to meet or to marginally exceed the minimum required temperature. **DO NOT OVERHEAT CIDEX® Solutions**, as overheating may increase vapors of the solution in the work environment. Solution temperature should be regularly monitored when heating CIDEX® Solutions.

Our customers may select from numerous heating systems on the market today that may be used to safely and gently warm CIDEX® Solutions for manual reprocessing. ASP has performed limited testing on several such commercially available heating systems and has provided the information below to serve as an example only. In this example, a UL certified heating mat, impervious to water, is used to gently heat a basin of CIDEX® Solution.

Pictured:

CIDEX® Solution Tray w/ Cozy Warming Pad & Rack
Part Number: GM-1
Contact: 312.226.2473

Note: Do not use a heating mat on a countertop or surface that is heat sensitive or the surface may discolor or change shape. **Temperatures below the mat may reach 65 °C.**

33 Technology Drive, Irvine, CA 92618 Tel: (800) 595-0200 Fax: (949) 581-5997
ADVANCED STERILIZATION PRODUCTS
Division of Ethicon, Inc.
a Johnson & Johnson company

When heating a basin of CIDEX® Solution, it is important to ensure that the temperature is stable so that the minimum temperature is reliably met while not overheating the solution. Temperature control may be attained by using a temperature controller.

A temperature controller may be used to measure the temperature of the CIDEX® Solution and to apply the appropriate amount of power to the heater to maintain a specified temperature. In this scenario, the controller is first plugged into an outlet near the heating mat, the heating mat is then connected to the output of the controller, and finally the controller's temperature probe is placed into the CIDIEX® Solution. The tray's lid may then be sealed over top of the cord, and the temperature may be adjusted to the value appropriate for manual reprocessing. It is highly recommended that the temperature of the CIDEX® Solution be measured with a calibrated thermometer prior to each disinfection cycle, and that this temperature value be logged with the result of the CIDEX® Solution Test Strip used to verify the Minimum Effective Concentration.

Pictured (Available from Amazon.com):

HC-810M: Finnex Digital Temperature Heater Controller
(ASIN: B002TMTA7G)

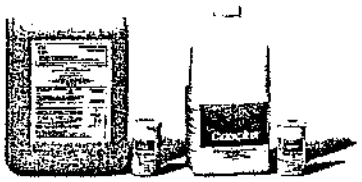
While ASP does not endorse Cozy Products or Finnex, we are providing this information as an example of a heating system that may be used to gently warm CIDEX® Solutions in a basin above their minimum temperatures. If you have any questions please call ASP Customer Care Center at 1-888-783-7723.

Sincerely,

Tracey Grenkoski
US Group Product Director, High-Level Disinfection

ASP
CIDEX®

HOW TO USE CIDEX® ACTIVATED DIALDEHYDE SOLUTION AND CIDEXPLUS® 28-DAY SOLUTION



For over 45 years, CIDEX® Solutions have been safely used by healthcare professionals for the high-level disinfection and sterilization of delicate heat-sensitive instruments because of their efficacy, materials compatibility, economy and ease of use.

Please read and follow the Instructions for Use (IFU) prior to using CIDEX® Solutions for important information, including contraindications, warnings and proper directions for use.

For technical information on CIDEX® Solutions, contact your local Advanced Sterilization Products sales representative or call ASP Customer Support at +1-888-783-7723.

ADVANCED STERILIZATION PRODUCTS
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* CIDEX® Sporicidal label reuse claims are based on an EPA protocol which challenges the solution three times per day in manual systems. Many healthcare workers challenge CIDEX® Solutions more than three times per day or use CIDEX® Solutions in soak washers. These practices cause dilution of the solution to levels below the MEC prior to its stated use life.

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1. Personal Protective Equipment

- Personal protective equipment must always be worn when handling contaminated instruments and equipment. Personal protective equipment includes disposable nitrile gloves, eye protection, face mask, and fluid-repellent gown. Once personal protective equipment is donned, you are ready to begin the disinfection/sterilization process.

2. Clean Instruments

- Contaminated instruments must be thoroughly cleaned prior to disinfection or sterilization since residual organic matter will decrease the effectiveness of the CIDEX® Solutions.
- To remove debris, thoroughly clean all instrument surfaces and the lumens of hollow instruments (e.g., endoscopes) with a mild protein-dissolving detergent such as ENZOL® Enzymatic Detergent Solution. CIDEX® Solutions are compatible with enzymatic detergents (e.g., ENZOL® Detergent Solution) which are mild in pH, low foaming, and easily rinsed from instruments. Detergents that are either highly acid or alkaline are contraindicated as cleaning agents since improper rinsing could affect the efficacy of the CIDEX® Solutions by altering their pH.
- Following cleaning, rinse instrument surfaces and lumens with large amounts of fresh water to remove residual detergent. Remove excess moisture from instrument prior to disinfecting or sterilizing. This will help prevent water from rapidly diluting the CIDEX® Solution below its minimum effective concentration (MEC).
- Refer to instrument manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing.

3. Activate solution

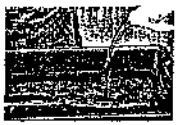
- Once the instruments have been properly cleaned, you are now ready to begin using the CIDEX® Solution. Prepare CIDEX® Solution for use by first adding the entire contents of the activator vial to the solution in the container. Shake well. Activated solution immediately changes color to green, only indicating that the activator has been added to the solution.
- Do not use activated solution beyond stated 14- or 28-day reuse life. NOTE: The activator contains a rust inhibitor. Do not add any other agent.
- Record the date of activation (mixing date) and expiration date in the space provided on the CIDEX® Solution container label, in a log book, or on a label affixed to the CIDEX® Solution tray or any secondary container. Log books are available through your local Advanced Sterilization Products sales representative.

4. Testing

- It is important to note that CIDEX® Solutions may expire prior to the reuse date stated on the label.* Do not rely solely on days in use. To determine if the correct MEC of the CIDEX® Solution is still present, CIDEX® Solutions must be tested prior to each use with the appropriate CIDEX® Solution Test Strip.
- It is recommended that CIDEX® Solutions be tested before each usage with appropriate CIDEX® Test Strips to verify that solution is above MEC. CIDEX® Solutions must be discarded after 14 or 28 days even if CIDEX® Test Strips indicate a concentration above the Minimum Effective Concentration (MEC).

5. Disinfection / Sterilization

- Immerse clean, dry instruments completely in the CIDEX® Solution. Fill all lumens of hollow instruments. To reduce exposure to glutaraldehyde vapors which can be irritating, cover the CIDEX® Solution tray or bucket with a secure lid. Soak instruments for the amount of time required for disinfection or sterilization. Please read and follow the Instructions for Use for complete instructions/information on soak times and temperature for disinfection and sterilization.
- Use CIDEX® Solutions in a well-ventilated area and in closed containers with tight-fitting lids. Failure to use CIDEX® Solutions without proper ventilation or engineering controls may result in an allergic reaction, urticaria (hives), or a rash. Use of CIDEX® Solutions without proper ventilation may also result in irritation to the respiratory tract and eyes, stinging sensation in the nose and throat or difficulty breathing.



6. Rinse Instruments

- For devices that have been sterilized: Remove instruments from solution using sterile technique and rinse thoroughly with sterile water. Please read and follow the Instructions for Use for complete rinsing instructions/information.
- Following disinfection, aseptically remove instruments from the solution and rinse instruments thoroughly, flushing the channels with potable or sterile water.
- Be sure to repeat this procedure twice, for a total of three rinses. Each rinse should be a minimum of one minute in duration, and a large volume of fresh water (e.g., two gallons) must be used for each rinse.
  Note: Please refer to the Instructions for Use for information on rinsing during processing in an automatic endoscope reprocessor.

7. Dry

- Once the instruments have been properly high-level disinfected or sterilized, dry the instruments. Disinfected or sterilized equipment should be used immediately or stored in a manner to minimize recontamination.
- Please read and follow the Instructions for Use for complete instructions/ information on drying flexible endoscopes when using potable water for rinsing, e.g., the use of alcohol for thorough drying. Refer to the instrument manufacturer's labeling for additional storage and/or handling instructions.

8. Disposal

- In compliance with the United States Environmental Protection Agency requirements, CIDEX® Solutions may be disposed of as an ordinary domestic waste rather than a hazardous waste. However, some state regulatory and local water board or sewer authorities may have certain restrictions on drain disposal of specific wastes from your facility.

Reorder No. 2266

CIDEX®

Activated Dialdehyde Solution (GLUTARALDEHYDE 2.4%)

INSTRUCTIONS FOR USE

A. INDICATIONS FOR USE USE

Sterilant: CIDEX® Activated Dialdehyde Solution is indicated for use as a sterilant when used or reused, according to Directions for Use, for up to a maximum of 14 days at 25°C with an immersion time of at least 10 hours.

1) High Level Disinfectant:

CIDEX Solution is indicated for use as a high level disinfectant when used or reused, according to Directions for Use, for up to a maximum of 14 days at 25°C with an immersion time of at least 45 minutes (Reuse section below).

2) Reuse Period

CIDEX Solution has also demonstrated efficacy in the presence of up to 5% organic soil contamination and a simulated amount of microbiological burden during reuse. CIDEX Solution can be reused for up to a maximum of 14 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in Directions for Use. DO NOT rely solely on days in use. Efficacy of this product during its use-life must be verified by the CIDEX Solution Test Strips to determine that the solution is above the minimum effective concentration (MEC) of 1.5% glutaraldehyde. Test the solution prior to each use. Use only CIDEX Solution Test Strips as they have been specifically designed to monitor CIDEX Solution MEC. Individual hospital results on the number of days of reuse will vary. Reuse of CIDEX Solution for up to a maximum of 14 days was determined through a standardized regulatory protocol and an analytical test procedure[1].

3) General Information on Selection and Use of Disinfectants for Medical Device Reprocessing

Choose a disinfectant with the level of antimicrobial activity that is appropriate for the reusable medical device. Follow the reusable medical device labeling and standard institutional practices. The following may be used as a guideline:

(a) Determine whether the reusable device to be reprocessed is a critical, semi-critical, or non-critical medical device.

A **critical medical device** presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use, enter the vascular system, or are otherwise used in normally sterile tissue of the body.

A **semi-critical medical device** makes contact with mucous membranes but does not usually penetrate normally sterile areas of the body.

A **non-critical medical device** contacts only intact skin during routine use.

(b) Determine the level of activity that is needed for the reusable medical device.

Critical Medical Device Sterilization is required (e.g.: cardiac catheters, scalpels, surgical instruments).

Semi-critical Medical Device Sterilization is recommended whenever practical, otherwise High Level Disinfection is acceptable (e.g.: GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.)

(c) Select a disinfectant that is labelled for the appropriate disinfectant level and is compatible with the reusable medical device. Follow directions for the disinfectant.

4) Microbial Activity

The following table indicates the spectrum of activity as demonstrated by testing of CIDEX Solution**

BACTERIA		FUNGI	VIRUSES	
SPORES	VEGETATIVE ORGANISMS		NON-ENVELOPED	ENVELOPED
Bacillus subtilis Clostridium sporogenes	Staphylococcus aureus Salmonella choleraesuis Pseudomonas aeruginosa Mycobacterium tuberculosis	Trichophyton mentagrophytes	Poliovirus Type 1 Rhinovirus Type 14 Adenovirus Type 2 Vaccinia	Coronavirus Cytomegalovirus Influenza virus Type A [WS/33] HIV-1 (AIDS Virus) Herpes simplex Type 1,2

**Testing was done after 14 days of simulated reuse using the U.S. EPA Reuse Protocol (see section G2 Reference Information).

5) Material Compatibility

CIDEX Solution is recommended for use with medical devices made from the materials shown below. Care must be taken with medical devices such as anesthesia and respiratory therapy tubing, dental mirrors and burrs. These devices may be damaged when cleaned with a highly alkaline detergent, poorly rinsed after disinfection, stored wet or dried at temperatures exceeding 40°C.

METALS
Chrome plate[1]
Copper[1]
Monel[1]
Nickel plate[1]
Nickel silver alloy[1]
Platinum[1]
Silver Solder[1]
Tungsten[1]
70-30 Solder[1]
Aluminum[2]
Gold Plate[2]
Silver Plate[2]
Anodized aluminum[5]
Brass[5]
Carbon Steel[6]
Stainless Steel[6]

PLASTICS
Polysulfone[1]
Teflon[1]
Polyethylene terephthalate (Polyester)[3]
Polymethylmethacrylate (Acrylic)[3]
Polystyrene[3]
Polyvinylchloride (PVC)[3]
Polycarbonate[4]
Acrylonitrile-butadiene-styrene (ABS)[6]
Nylon[6]
Polyethylene[6]
Polypropylene[6]

ELASTOMERS
Polychloroprene (Neoprene)[1]
Polyurethane[1]
Black natural rubber[6]
Red natural rubber[6]
Silicone rubber (Silastic)[6]

NOTE:

1 Represents 8 hours of continuous contact with CIDEX Solution.
2 Represents 10 hours of total contact with CIDEX Solution over 20 disinfection cycles.
3 Represents 20 hours of total contact with CIDEX Solution over 20 disinfection cycles.
4 Represents 40 hours of total contact with CIDEX Solution over 40 disinfection cycles.
5 Represents 144 hours of continuous contact with CIDEX Solution.
6 Represents 336 hours or greater of continuous contact with CIDEX Solution.

6) Cleaning Agent Compatibility

Detergents that are either highly acidic or alkaline are contraindicated as cleaning agents since improper rinsing could affect the efficacy of the CIDEX Solution by altering its pH.

Rinse devices completely prior to immersion in CIDEX Solution.

B) CONTRAINDICATIONS

- CIDEX Solution should NOT be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g.: heat, ethylene oxide, or hydrogen peroxide gas plasma.
- CIDEX Solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters, cannulae used for intraocular lens replacement and other types of single use devices).
- CIDEX Solution should NOT be used to achieve high level disinfection of a semi-critical device when sterilization is practical.
- CIDEX Solution should not be used for sterilization of rigid endoscopes which device manufacturers indicate are compatible with sterilization processes that can be biologically monitored (e.g. steam, dry heat, ethylene oxide, hydrogen peroxide gas plasma).

C) WARNINGS

CIDEX ACTIVATED DIALDEHYDE SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS
Keep out of reach of children. This product is not to be sold, distributed, or used for any other purpose.

CAUTION
Contains Glutaraldehyde
Harmful by inhalation and if swallowed.
Irritating to respiratory system and skin.
Risk of serious damage to eyes.
May cause sensitisation by inhalation and skin contact.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable protective clothing, gloves and eye/face protection.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

HARMFUL
Use only in well-ventilated areas (refer to the Material Safety Data Sheets for additional information).
Avoid release to the environment.

1) Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing.
2) Avoid contamination of food.
3) Refer to Material Safety Data Sheet (MSDS) for the following.

Skin Contact: Brief contact may cause itching with mild to moderate local redness. Prolonged contact may result in staining of the skin. Contact may aggravate existing dermatitis. Repeated skin contact may cause a cumulative dermatitis, may cause skin sensitization in a small proportion of individuals and present as an allergic contact dermatitis. This usually results from contact with the liquid but occasionally there may be a reaction to glutaraldehyde vapor.

Eye Contact: If not rinsed properly, liquid will cause conjunctivitis, seen as redness and swelling of the conjunctiva. Severe corneal injury may develop which could permanently impair vision if prompt first aid and medical treatment are not obtained. Vapor may cause stinging sensations in the eye with excess tear production, blinking and possibly a slight redness of the conjunctiva.

Inhalation: May cause sensitisation by inhalation. Vapor is irritating to the respiratory tract, causing stinging sensations in the nose and throat. May cause bleeding from the nose, coughing, chest discomfort and tightness,

difficulty with breathing and headache. Inhalation of vapor may cause asthma-like symptoms (chest discomfort and tightness, difficulty with breathing). Glutaraldehyde has been reported to cause occupational asthma and may aggravate existing asthma and inflammatory or fibrotic pulmonary disease. Heating the solution may result in more severe irritant effects.

Ingestion: May cause irritation or chemical burns of the mouth, throat, oesophagus and stomach. There may be discomfort or pain in the mouth, throat, chest and abdomen, nausea, vomiting, diarrhea.

FIRST-AID MEASURES:
Skin: Immediately remove contaminated clothing and shoes. Wash skin thoroughly with soap and water. Obtain medical attention. Wash clothing before reuse. Discard contaminated leather articles such as shoes and belt.

Eyes: Immediately flush eyes with water and continue washing for at least 15 minutes. DO NOT remove contact lenses during washing procedure. Obtain medical attention without delay, preferably from an ophthalmologist.

Inhalation: Remove to fresh air. Give artificial respiration if not breathing. If breathing is difficult, oxygen may be given by qualified personnel. Obtain medical attention.

Ingestion: Do not induce vomiting. Wash mouth out thoroughly with water. Drink copious amounts of a demulcent (liquid which soothes irritation) such as milk. Obtain medical attention without delay.

Note to Physician: Probable mucosal damage from oral exposure may contraindicate use of gastric lavage.

For further Hazard information please refer to the Material Safety Data Sheet. See Section G below.

D) PRECAUTIONS

1) Use gloves of appropriate type and length, eye protection, face-mask and fluid-resistant gowns or aprons. When using latex rubber gloves, the user should double glove and/or change single gloves frequently; e.g., after 10 minutes of exposure. For those individuals who are sensitive to latex or other components in latex gloves, 100% synthetic copolymer gloves, nitrile rubber gloves or butyl rubber gloves may be used. The use of neoprene or polyvinyl chloride (vinyl) gloves is not recommended, as glutaraldehyde may be rapidly absorbed by these materials.

2) Contaminated, reusable medical devices **MUST BE THOROUGHLY CLEANED** prior to immersion in CIDEX Solution, since residual contamination will decrease effectiveness of the disinfectant.

3) The user MUST adhere to the **Directions for Use** (Section E) since any modification will affect the safety and effectiveness of the disinfectant.

4) The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDEX Solution.

5) The use of CIDEX Solution in Automated Endoscope Reprocessors (AER) **must be part of a validated reprocessing procedure provided by the reprocessor manufacturer.** Monitor Glutaraldehyde concentration to ensure that it is above the MEC. Test the solution prior to each use. CIDEX Solution Test Strips must be used for this purpose.

6) Use CIDEX Solution in a well-ventilated area in closed containers with tight fitting lids. Use in local exhaust hoods or in ductless fume hoods/portable ventilation equipment, which contain filter media that absorb glutaraldehyde from the air, if adequate ventilation is not provided by the existing air conditioning system.

E) DIRECTIONS FOR USE

CIDEX Solution is intended for use in the processing of critical and semi-critical medical devices that are to be used on humans.

Do not dilute.

CIDEX Solution can be used in Automated Endoscope Reprocessors (AER) where approved by the manufacturer of the AER. CIDEX Solution is intended for use in manual (bucket and tray) systems (see D6 above) made from polypropylene, acrylonitrilebutadiene-styrene (ABS), polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics.

1) Activation

Activate the CIDEX Solution by adding the entire contents of the Activator Vial, which is attached to the CIDEX Solution container. Shake well. Activated solution immediately changes color to green only indicating that the activator has been added to the solution. Record the date of activation (mixing date) and expiration date on the container label in the space provided, in a logbook or a label affixed to any secondary container used for the activated solution. Test the activated solution prior to use with CIDEX Solution Test Strips.

2) Cleaning

Feces, mucous, tissues, blood and other body fluids must be thoroughly cleaned from surfaces and lumens of devices before processing in CIDEX Solution. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal.

Thoroughly clean, rinse and rough dry devices before immersing in CIDEX Solution. Clean and rinse the lumens of hollow instruments before filling with CIDEX Solution.

Refer to the reusable medical device manufacturers labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

3) Usage

(a) Test the solution to ensure that the glutaraldehyde concentration is above its MEC. Test the solution prior to each use. CIDEX Solution Test Strips must be used for this purpose. Although test strips from other manufacturers may give a color reaction with CIDEX Solution, their use has not been validated with this product. Only CIDEX Solution Test Strips can be used with CIDEX Solution as they monitor the MEC of 1.5%.

(b) Immerse cleaned and rough dried medical devices completely in the CIDEX Solution, filling all lumens. Check with the medical device manufacturer to ensure that the device is capable of being completely submersed in liquid before being placed in CIDEX Solution.

(c) Leave medical devices completely immersed for the required time at the appropriate temperature (see section A, Indications for Use).

(d) At the end of the required time remove medical devices from the solution using aseptic technique.

(e) Rinse thoroughly with the appropriate quality of water (sterile or potable) following the rinsing instructions below.

(f) Reuse CIDEX Solution in accordance with the conditions in section A2, Reuse Period.

4) Rinsing Instructions

Following removal from CIDEX Solution, thoroughly rinse the medical device by immersing it completely in three separate copious volumes of water. Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Water should be flushed through all lumens during each separate rinse, unless otherwise noted by the endoscope manufacturer.

Refer to the reusable medical device manufacturer's labeling for additional instructions. Check with the applicable AER manufacturer to ensure that these minimum rinsing requirements are met.

(a) Sterile Water Rinse

The following are examples of medical devices that should be rinsed with sterile water, using aseptic technique when rinsing and handling:

1. Medical devices intended for use in normally sterile areas of the body;
2. Medical devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on hospital procedures and;
3. Bronchoscopes, if feasible, due to a risk of atypical Mycobacteria contamination from potable water supply.

(b) Potable Water Rinse

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the medical device with waterborne organisms e.g., pseudomonads, atypical mycobacteria etc.

A medical device (e.g., colonoscope) that is not completely dried provides an ideal environment for rapid colonization of bacteria. Additionally, mycobacteria are highly resistant to drying; therefore, rapid drying will avoid possible colonization but may not result in a medical device free from atypical mycobacteria. Although these bacteria are not normally pathogenic in patients with healthy immune systems, patients infected with HIV (Human Immunodeficiency Virus) patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water. Potable water should be monitored on a regular basis and its microbiological quality controlled.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these water-borne bacteria from the potable water source. Contact the manufacturer of the filter for instructions on preventive maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

5) Monitoring of Disinfectant to Ensure Specifications Are Met

During the use of CIDEX Solution it is recommended that a thermometer and timer be used to ensure that the optimum usage conditions are met. In addition, it is necessary to test CIDEX Solution with the CIDEX Solution Test Strips. Test the solution prior to each use. This is to ensure that the glutaraldehyde concentration is above its minimum effective concentration. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 8.2 to 9.2. Method of determining pH requires a specific methodology (see G2 Reference Information).

6) Post-Processing Handling and Storage of Reusable Medical Devices

Processed medical devices are either to be immediately used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the medical device manufacturers' labeling for additional storage and/or handling instructions.

F) STORAGE CONDITIONS AND EXPIRATION DATE

1) Prior to activation, CIDEX Solution should be stored in its original sealed container at controlled room temperature 15°-30°C (59-86°F). In common with other chemicals it is good practice to store this product out of direct sunlight.

Once the CIDEX Solution has been activated, it should be stored in the original container until transferred to the closed containers in which the immersion is to take place.

Containers should be stored in a well-ventilated, low traffic area at controlled room temperature.

2) The expiration dates of the unactivated CIDEX Solution and activator will be found on the container.

3) The use period for activated CIDEX Solution is for up to a maximum of 14 days following activation or, as indicated by the CIDEX Solution Test Strips.

G) ADDITIONAL SAFETY AND TECHNICAL PRODUCT INFORMATION

1 Safety Information

Safety information about CIDEX Solution (such as the MSDS) can be obtained from:
Advanced Sterilization Products at (888) 783-7723, or by contacting your local Advanced Sterilization Products sales representative.

For further Hazard information please refer to the Material Safety Data Sheet.

2 Reference Information

Glutaraldehyde Titration Method
U.S. EPA Reuse Protocol
Test method for pH in CIDEX
Favero M, Bond W. Chemical disinfection of medical surgical material. In: S.S. Block, ed. Disinfection, sterilization and preservation, 5th ed. Williams and Wilkens, 2000. Chapter 43

H) USER PROFICIENCY

The user should be adequately trained in the decontamination and reprocessing of medical devices and the handling of toxic substances such as liquid chemical sterilants/high level disinfectants.

I) DISPOSAL INFORMATION

CIDEX Solution Disposal
Discard residual solution in drain or per your facility policy. Flush thoroughly with water.

Container Disposal
Do not reuse empty container. Rinse with water and dispose per your facility policy.

J) HOW SUPPLIED

Reorder No.	Description	Case Contains
2266	4.7L	4 x 4.7L containers/case
2920	CIDEX® Solution Test Strips	60 strips/container; 2 containers/case
2927	CIDEX® Solution Test Strips	15 strips/container; 2 containers/case

References supplied upon request

See section G2 Reference Information.

How to Obtain the Instructions for Use

You can obtain the **Instructions for Use** by the following methods:

- WEB SITE: The **Instructions for Use** are available on www.e-ifu.com
- FAX-ON-DEMAND SYSTEM: Dial 888-783-7723 and follow the prompts.

Medos International Sàrl
Chemin-Blanc 38
CH-2400 Le Locle
Switzerland

Marketed By:

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a Johnson & Johnson company

33 Technology Drive, Irvine, CA 92618
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For technical information and/or information regarding safety and effectiveness, call 1-888-783-7723.

Made in U.K.

A. Intended Use

The CIDEX® Solution Test Strips are semi-quantitative chemical indicators for use in determining whether the concentration of glutaraldehyde, the active ingredient in CIDEX® Activated Dialdehyde Solution, is above or below the minimum effective concentration (MEC) established for CIDEX Activated Dialdehyde Solution.

CIDEX Solution Test Strips cannot be used to validate the sterilization or disinfection process.

B. Explanation of the Test

CIDEX Solution Test Strips are developed exclusively for monitoring the minimum effective concentration (MEC) of CIDEX Activated Dialdehyde Solution which has been activated for use. It is recommended that activated solution be tested daily before each usage with the test strips in order to guard against dilution, which may lower the glutaraldehyde level of the solution below its MEC.

CIDEX Solution Test Strips will NOT detect failure to activate the solution.

WARNING: Do not use CIDEX Activated Dialdehyde Solution beyond its maximum 14 day use life.

C. Chemical Principle of the Test Procedure

Glutaraldehyde reacts with sodium sulfite in the test strip to form a sulfite addition product and an equivalent amount of base (STEP 1). If sufficient glutaraldehyde is present, the â crease in pH causes a color change in the pH indicator (STEP 2).

STEP 1

$HCO(CH_2)_3CHO + 2Na_2SO_3 + H_2O \rightarrow$

Glutaraldehyde — Sodium sulfite — Water

$(CH_2)_3(CH(SO_3Na)OH)_2 + 2NaOH$

Sulfite addition product — Sodium hydroxide

STEP 2

NaOH + pH sensitive dye ➥ purple dye color

When the concentration of glutaraldehyde is sufficient, a color change from orange to purple occurs on the reagent pad at the end of the strips.

D. Reagents/Storage

The reagent pad at the end of the test strip is composed of paper impregnated with two reactive agents, sodium sulfite and pH-sensitive dye.
Store CIDEX Solution Test Strips in the original bottle with the cap tightly closed. Store at controlled room temperature, 15°-30°C (59°-86°F), and in a dry place.
The shelf life (expiration date) for the unopened CIDEX Solution Test Strips is stamped on the immediate container label. When opening the bottle for the first time, record the date opened in the space provided on the label.

PRECAUTIONS:

- **Do not use any remaining strips 90 days after opening the bottle. Do not leave the test strip bottle open for more than 30 minutes. Improper storage or use of test strips may result in false readings.**

LC-B2920-003 Rev. E
Cidex® Solution Test Strips IFU
Enlarged 125%
Size: 72 x 582mm
Colors: Black
Date: 5/21/04

- **To properly seal the test strip bottle, press down firmly with the palm of your hand on the lid. Please make sure that the bottle is closed completely.**
- **Do not refrigerate or freeze.**
- **Protect strips from exposure to light, heat, and moisture.**
- **Tightly re-cap test strip bottle after each use to minimize exposure to humidity.**

E. Specimen Collection and Preparation

CIDEX Solution Test Strips can be used to test activated solution directly in the tray, bucket or other container holding the solution. When this is not feasible, remove a sufficient volume of CIDEX Solution to fully submerge the CIDEX Test Strip indicating pad area, and place into a clean plastic container (polyethylene or polypropylene). Appropriate safety precautions should be taken according to label instructions and the Material Safety Data Sheet.

F. Directions for Use

1. Ensure that the CIDEX Activated Dialdehyde Solution has been activated according to its own Instructions for Use.
2. Always note the date the bottle was opened and the “do not use after” date in the space provided on the bottle.
3. Ensure that appropriate safety precautions are observed when testing CIDEX Activated Dialdehyde Solution, refer to product labeling and the Material Safety Data Sheet for CIDEX Activated Dialdehyde Solution.
4. Remove one Test Strip from the bottle and replace the bottle cap immediately.
5. Use a watch or timer to monitor the following steps.
6. Timing control is critical to accurate reading.
7. **Completely Submerge** indicating pad at the end of the test strip into the container of the activated solution being tested. Hold for **three seconds and remove.** Do not leave the strip in the test solution for longer than three seconds or “stir” the test strip in the solution. Incorrect dipping technique, such as swirling the test strip vigorously in the solution, will wash off the reagents in the test strip pad. This can cause a lack of purple color formation (FAIL) when testing a solution that will normally test as PASS.
8. **Remove** excess solution from the indicating pad by standing the strip upright on a paper towel. Do not shake the strip after removal. When removing excess solution, incorrect technique, such as violently shaking the test strip and/or blotting the test strip with the pad face down against a paper towel, can remove the reagents and solution. This can cause FAIL results for solutions that will normally test as PASS.
9. **Read** the results of the color reaction present on the indicating pad at **75 seconds after the test strip is removed from the solution.** If read in less than 75 seconds, the color change may be incomplete and may be interpreted incorrectly. If read past 75 seconds, color will gradually change to indicate “FAIL”.

   To indicate an effective concentration of the solution, the indicating pad will be completely purple. Any shade of purple is acceptable; the intensity will vary due to concentration variation. If **any orange** appears on the indicating pad apart from the top line, the solution is below the MEC and should be discarded. Refer to the color chart on the test strip bottle for interpretation of test results. Record the result of the test in a suitable log book.

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See Section I, Test Results Interpretation, for additional important information on the use of this product.

10. **Dispose** of the used Test Strip in a waste bin or per hospital policy.

G. Materials Required

The following materials are not provided with the CIDEX Solution Test Strips but will be needed for the test:

- watch or timer
- paper towel
- a clean polyethylene or polypropylene container will be required to hold the solution sample if the solution cannot be tested directly in the tray, bucket or container in which it is being held.

H. Quality Control Procedures

1. **Preparation of Control Solutions**
   To prepare positive and negative control solutions for testing, first verify that the labeled expiration date for the unactivated solution is appropriate. Activate the solution according to labeling instructions. This freshly activated, full strength solution may be used as a positive control. To prepare a negative control, dilute one part of full strength activated solution with one part of water. Label each control solution appropriately.
2. **Testing Procedure**
   Following the Directions for Use, submerge three test strips in each of the above freshly prepared solutions for three seconds each. Remove. The three strips dipped in the full strength positive control solution should exhibit a complete purple color on the indicating pad at 75 seconds. The three strips dipped in the diluted negative control should either remain completely orange or exhibit an incomplete color change to purple when read at 75 seconds. Refer to the color chart on the test strip bottle for interpretation of results.
3. **Testing Frequency**
   It is recommended that the testing of positive and negative controls be performed on each newly opened test strip bottle of CIDEX Solution Test Strips. After this initial testing, it is recommended that testing of freshly prepared positive and negative controls be performed on a regular basis as established by your own quality control procedures and program. This testing program will serve to minimize errors between different users, use of outdated materials or product that has been improperly stored or handled.
4. **Unsatisfactory QC Test Performance**
   If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, discard the remaining strips. **Do Not Use Strips.** For technical product information, contact Advanced Sterilization Products at 1-888-783-7723.

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I. Test Results Interpretation

Following the three second submersion in the activated solution being tested, remove excess solution from the pad by standing the strip upright on a paper towel. The CIDEX Solution Test Strip should then be compared to the color chart provided on the test strip bottle at 75 seconds. The entire indicating pad must be completely purple to pass the test indicating an effective concentration of the solution. If any orange appears on the indicating pad apart from the top line, this is a failure, verifying the solution is below MEC and should be discarded.

As the MEC of CIDEX Activated Dialdehyde Solution is approached during its use life, the test strip will give some PASSES and some FAILS. This is due to the safety margin provided by the test strip.

The solution must be discarded if the Test Strip indicates FAIL.

J. Limitations

Although CIDEX Solution Test Strips may give a color reaction with glutaraldehyde-based disinfectants from other manufacturers, their use is limited to the CIDEX Activated Dialdehyde Solution. Disinfectants from other manufacturers may claim different MECs which will lead to inaccurate test results using CIDEX Solution Test Strips.

CIDEX Solution Test Strips will not work with CIDEX® OPA Solution or CIDEXPLUS® Solution.

CIDEX Solution Test Strips will <u>not</u> detect failure to add the activator to the CIDEX Activated Dialdehyde Solution.

K. Performance Characteristics

The performance characteristics of CIDEX Solution Test Strips are based on testing the strips using samples of CIDEX Activated Dialdehyde Solution with known concentrations of glutaraldehyde at the MEC and above the MEC. The analytical method used to determine the glutaraldehyde concentrations in these samples is an analytical titration method[1]. The performance of CIDEX Solution Test Strips has been designed to indicate FAIL 100% of the time when the concentration of glutaraldehyde falls to 1.5%.

The accuracy and sensitivity limit of CIDEX Solution Test Strips is + 0.25%. Thus at concentrations of 0.25% above the MEC, the test strips will indicate FAIL about 25% of the time and PASS about 75% of the time. This provides the user with a high margin of safety.

L. Warnings & Precautions

1. Always follow the Instructions for Use.
2. THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY. If the container is left open for more than 30 minutes, discard the Test Strips and use a fresh bottle of new Strips.

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Enlarged 125%
Size: 72 x 582mm
Colors: Black
Date: 5/21/04

3. Test Strips should not be returned to the bottle after being removed due to their moisture sensitivity - dispose of any unused Test Strips.
4. Keep out of reach of children.
5. Do not ingest the Strip and/or expose it to the eye.
6. Chemical indicators such as CIDEX Solution Test Strips cannot be relied upon as a means of validating the sterilization or disinfection process. Chemical indicators can only verify if the MEC is present.
7. Each Test Strip must be discarded after use and not reused.
8. Ensure that appropriate safety precautions are observed when testing CIDEX Activated Dialdehyde Solution, refer to product labeling and the Material Safety Data Sheet for CIDEX Activated Dialdehyde Solution.

M. Disposal

Dispose of used or expired Test Strips and their bottle in a waste bin or per hospital policy.

N. Bibliography

1. Advanced Sterilization Products
   Standard Test Method Number
   TP-25118-001 (available upon request).

O. How Supplied

PRODUCT CODES	DESCRIPTION	PACKAGE INFORMATION
2920	CIDEX® Solution Test Strips	60 Strips/Bottle 2 Bottles/Shipper
2927	CIDEX® Solution Test Strips	15 Strips/Bottle 2 Bottles/Shipper

Marketed By:

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.
33 Technology Drive, Irvine CA 92618-9824

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Made in UK
For technical information
call 1-888-783-7723.

LC-B2920-003 Rev. E
Cidex® Solution Test Strips IFU
Enlarged 125%

Size: 72 x 582mm
Colors: Black

Date: 5/21/04

LC-B2920-003 Rev. E
Cidex® Solution Test Strips IFU
Enlarged 125%

Size: 72 x 582mm
Colors: Black

Date: 5/21/04

Cidex® Solution Test Strips

Composition: CIDEX® Solution Test Strips consist of sodium sulfite and dyes impregnated and dried on filter paper.

STORAGE

IMPORTANT: Keep cap tightly closed. Store bottle at controlled room temperature 15°-30°C (59°-86°F) and in a dry place. **CAUTION:** Do not use after 90 days of opening the bottle.

Marketed By:

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For technical information
call 1-888-783-7723

<Insert Date>

Important End-User Customer Notice of Product Obsolescence: CIDEXPLUS® 28 Day Solution

Dear Valued Customer,

In an effort to transition healthcare professionals to the latest ASP products in instrument reprocessing, ASP has made the decision to obsolete CIDEXPLUS® 28 Day Solution, a 3.4% Glutaraldehyde, in 2014. The majority of our customers already choose to use glutaraldehyde-free solutions and we want to support this shift. The ASP mission is to provide best-in-class infection prevention products and solutions for customers and their patients. By supporting our customers' choice to use glutaraldehyde-free solutions, we are doing just that!

Please notify all materials managers and department directors with the following information on part numbers being discontinued in 2014:

Part Number	Description
2683	CIDEXPLUS® 28 Day Solution: 1 Quart, 4/case
2785	CIDEXPLUS® 28 Day Solution: 1 Gallon, 4/case

Distributors will be able to purchase the above two products from ASP until the end of 2013. There may be limited supply available through your distributor in January 2014. Please check with your distributor to find out product availability.

ASP will continue to provide product support for CIDEXPLUS® 28 Day Solution until the remaining product inventory has been used or has expired. In addition, ASP will continue to sell test strips for use with CIDEXPLUS® 28 Day Solution, part number 2924.

Recommended Replacement Products: CIDEX® OPA Solution, Part Number 20390, is trusted by hospitals all the world over for providing cost-effective high-level disinfection for a wide range of endoscopes and other healthcare instruments. CIDEX® OPA Solution features include:

- Glutaraldehyde-free (0.55% *ortho*-phthalaldehyde) high-level disinfecting solution
- Rapid 5-minute soak time at 77 °F/25°C in an automated endoscope reprocessor
- Twelve minute soak time at 68 °F/20°C for manual reprocessing
- Shorter disinfection time than glutaraldehyde
- Low vapor pressure for minimal inhalation exposure risk

If you prefer to use glutaraldehyde, ASP will continue to offer CIDEX® Activated Dialdehyde Solution, Part Number 2266.

For more product information on CIDEX® Solutions, visit our website at www.aspjj.com/us/products/high-level or contact your local ASP representative.

We would like to thank you for your commitment to ASP and for your continued **trust** in the CIDEX® Solutions brand. If you have any questions, please contact 888-783-7723 or visit www.aspjj.com.

Sincerely,

Anthony Bishop

Vice President, Global Marketing

33 Technology Drive, Irvine, CA 92618. Tel: 949.581.5799. Fax: 949.581.5997

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Procedures for Decontamination by Autoclaving

Purpose:

Biohazardous waste material and sharps containers generated within research and teaching facilities are required to be decontaminated in laboratory (or departmental) autoclaves and disposed of using the appropriate waste streams.

The procedures below serve as guidelines to help autoclave users ensure safe and effective processing.

1. **Select appropriate containers or bags for collecting materials to be autoclaved.**

   ✸ **For biohazardous dry solid materials**

   a. Collect in polypropylene AUTOCLAVE bags:

   BSL-1 waste → Clear bags, no symbol
   BSL-2 waste → Orange bags, symbol
   BSL-3 waste → Red bags, symbol

   b. **DO NOT** use the red bags that come with the Regulated Medical Waste (RMW) boxes for initial waste collection. They are not meant to be autoclaved.

   c. Ensure that bags are free of sharp objects that may puncture bags. Autoclave bags are tear resistant, but can be punctured or burst in the autoclave.

   d. Fill bags only 2/3 full.

   e. Ensure adequate steam penetration by creating an opening of at least one inch in the bag's closed top.

   f. On autoclaves which have no Prevacuum cycle, water can be carefully added to bags of waste run on Solids/Gravity cycle *if needed to achieve effective decontamination*. (Steam created inside the bag during processing aids in reaching appropriate temperature.)

☑ **POLYPROPYLENE AUTOCLAVE BAG**

⊗ **SHARPS PENETRATING BAG**

☑ **CLOSURE**

⊗ **CLOSURE**

⊗ **OVERFILLED**

✡ **For biohazardous sharps:**

a. Collect in commercially available Sharps containers with lids or closures. Containers must not be tightly sealed shut AND MUST NOT BE OVERFILLED.

✸ **For biohazardous liquids:**

a. Never autoclave plastic materials of uncertain heat stability. Collect liquid in glassware or plasticware that is suitable for autoclaving.

b. Do not fill containers more than 2/3 full.

c. Make sure that caps are loose or use vented closures.

d. Never put sealed containers in an autoclave. They can explode. Large bottles with narrow necks may also explode or boil over if filled too full of liquid.

e. Never put materials containing solvents, corrosives or radioactive materials in the autoclave (e.g., phenol, chloroform, pyridine, or bleach).

☑ **PROPER CLOSURES**

⊗ **NO PRESSURIZED VESSELS**

2. Place waste bags or containers with liquids in a secondary container.

a. Make sure your plastic secondary container is suitable for autoclaving. Polyethylene or HDPE cannot be autoclaved.

b. Polypropylene, polycarbonate or stainless steel pans are typically used for secondary containment. See Nalgene Labware's Autoclaving Web page for additional plastic considerations.

c. Select a container with the lowest sides possible for the autoclave. This will promote penetration of steam and will collect any leakage or overflow of liquids.

d. Make sure pan contains the entire volume of waste—no spilling over sides.

e. Leave space between items/bags to allow steam circulation.

f. Safely transport the material to the autoclave.

☑ **STAINLESS STEEL**

☑ **NALGENE PAN**

⊗ **OVERFILLED PAN**

3. Place a Class 5 Chemical Indicator (CI) in the waste load to check operating parameters.

☑ **5 Chemical Integrator with Extender**

a. If you are using a challenge test pack containing the CI, place it with the waste.

b. If you are using a CI with no pack, place it WITHIN the load of waste in a position where it will encounter the greatest challenge to steam penetration.

c. Avoid direct exposure to waste by using CIs with extenders, or make one yourself by straightening and trimming a coat hanger, and attach the CI to one end with autoclave tape. Place carefully to avoid puncture of bags.

d. Not every container of waste per load must receive a CI. Place CI in the container which occupies the most challenged position in the load (i.e., if running 3 bags, put CI in center bag).

4. Load the autoclave.

☑ **CHECK DRAIN SCREEN**

a. Review the Standard Operating Procedures (SOP) for the autoclave unit. Training must be provided for any new autoclave operators.

b. Check the drain screen at the bottom of the chamber before loading the autoclave.

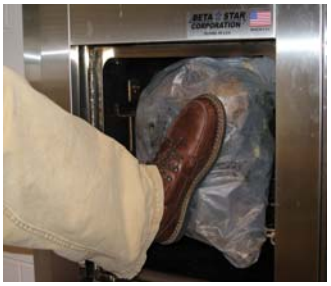
c. Place a piece of autoclave tape (Class I Chemical Indicator) on the outside of the container or bag. Black stripes appearing on the tape give a visual verification that the material has been processed.

☑ **AUTOCLAVE TAPE**

d. If an autoclave is available, place the load + its secondary container in the autoclave chamber for processing.

- DO NOT OVERFILL THE CHAMBER!
- Load should not touch chamber walls
- DOOR should be clear of obstructions before closing

⊗ **OVERFILLED CHAMBER**



e. Whenever possible, autoclave the load immediately after preparation. Do not leave unprocessed items in the autoclave overnight.

f. If the autoclave is in use, store waste, in a secondary container, in a designated holding area, and decontaminate at the earliest possible time.

4. Choose an appropriate cycle.

CYCLE TYPE & TYPICAL PARAMETERS	RECOMMENDED FOR:
LIQUIDS **STERILIZE TEMP = 121° C** **STERILIZE TIME = 30-60 min.** **COOL TIME =40 min.** **RUN TIME = 70-100 min.**	• Type I borosilicate glass containers with vented closures; 2/3 full only • Liquid Media • Nonflammable liquids • Aqueous solutions • Liquid biowaste
	NOT RECOMMENDED FOR DRY ITEMS THAT DON'T REQUIRE A SLOW EXHAUST
SOLIDS / GRAVITY **STERILIZE TEMP = 121° C** **STERILIZE TIME = 30 to 40 min.** **DRY TIME =0 to 30 min.** **RUN TIME =45 to 80 min.**	• Glassware: -Type I borosilicate - empty & inverted - no tight or impermeable closures • Dry hard items, either unwrapped or in porous wrap • Metal items with porous parts • Other porous materials
	NOT RECOMMENDED FOR LIQUIDS OR MEDIA THAT REQUIRE A SLOW EXHAUST
PRE-VACUUM **STERILIZE TEMP121° C** **STERILIZE TIME = 30 to 45 min.** **COOL TIME = 2 to 5 min.** **RUN TIME 40 to 55 min.**	• Glassware that must be sterilized upright &/or can trap air • Wrapped dry items that can trap air • Pipette tip boxes • Sharps decontamination (in collection containers) • Biohazard waste decontamination (in autoclave bags; can be wet & dry tubes, plates, etc.)
	NOT RECOMMENDED FOR LIQUIDS OR MEDIA, LIGHTER WEIGHT PLASTIC CONTAINERS OR DRY ITEMS WHICH WILL COLLAPSE IN A VACUUM

☑ **LIQUID CYCLE**

⊗ **LIQUID RUN ON SOLIDS CYCLE—** (NOTE BOIL-OVER IN CHAMBER FLOOR PLUS NO SECONDARY CONTAINER)

☑ **PREVAC CYCLE**

5. Please note this important information:

a. For both DRY and LIQUID biohazardous waste materials, cycle times must be set for a minimum of 30 minutes @ 1210C, 15 psi.

b. LARGER VOLUMES OF LIQUIDS AND LARGER LOADS OF SOLIDS REQUIRE LONGER STERILIZATION TIMES.

c. LIQUIDS MUST BE AUTOCLAVED WITH SLOW EXHAUST.

RECOMMENDED STERILIZATION TIMES PER VOLUME FOR LIQUID CYCLES

Volume of Liquid in One Container	Minimum Recommended Sterilize Time at 121° C
75 ml	25 minutes
250 ml	30 minutes
500 ml	40 minutes
1000 ml	45 minutes
1500 ml	50 minutes
2000 ml	55 minutes
>2000 ml	55 + 10 min. / L

6. Fill out the autoclave use log (link) and be aware of required cycle times. Record your name, date, time, cycle to be run, etc. The results of the load verification results must also be recorded on this log.

☑ **SIGN AUTOCLAVE USE LOG**

7. Always employ the following safety guidelines when the autoclave cycle is finished:

a. Wear personal protection equipment:
- Lab coat
- Eye protection (when removing load)
- Closed-toe shoes
- Heat-resistant gloves to remove items, especially hot glassware

☑ **USE REQUIRED PPE**

b. Never open an autoclave unless the chamber pressure = 0.

c. Open the door cautiously. Stand behind the door or beside the unit and slowly crack it open no more than ½". Allow all steam to escape by waiting at least 10 minutes before unloading the material. CAUTION: Material will still be HOT!

d. Let liquids stand 10–20 minutes after the autoclave is opened. Superheated liquids can boil over and damage the autoclave and cause personal injury.

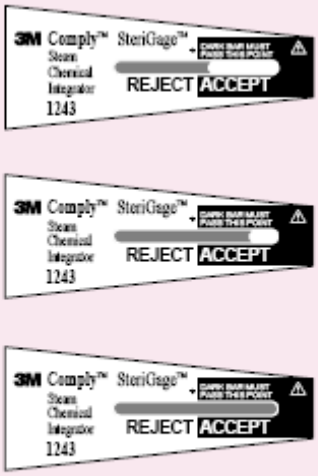
e. Do not override autoclave's built-in safety control features under any circumstances. If a problem occurs, contact the responsible technician.

8. **Verify operating parameters by checking for color change on Chemical Indicator strip.**

   - See example on right for 3M™ Comply Chemical Indicators.
   - See EHSS website to download SOP for Chemical Indicators (CI).

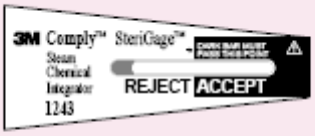
☑ **CHEMICAL INTEGRATOR VERIFICATION**

ACCEPT



The color bar has reached the ACCEPT window in all three samples shown above, indicating that the necessary conditions for sterilization have been met.

REJECT



The color bar is in the REJECT window, indicating that the necessary conditions for sterilization have not been met.

9. **Properly dispose of materials that have been successfully decontaminated as verified by Chemical Indicator strip.**

   a. Discard BSL-1 decontaminated waste (contained in clear bags with no biohazard symbol) into the regular trash.

   b. Place BSL-2 or BSL-3 decontaminated waste (contained in orange bags or bags with biohazard symbol) and ALL Sharps containers into Regulated Medical Waste boxes lined with red biohazard bags.

   c. Decontaminated biohazardous liquids may be poured down the drain.

   d. Loads that do not pass verification must autoclaved again and shown to be successfully decontaminated by CI verification before disposal.

   e. Causes of all CI verification failures must be determined and corrected, or reported to the responsible technician who will initiate corrective action.

   NOTE: The stripes on autoclave indicator tape changing from light to dark does not ensure that decontamination conditions were successfully met, but serves only as a visual indicator of processed (heat-exposed) versus non-processed items.

☑ **REGULATED MEDICAL WASTE**

10. **Perform required verification testing for your autoclave.**

    a. Use Biological Indicator (BI) testing for:
    - Verifying proper function of newly installed autoclaves

☑ **BIOLOGICAL INDICATOR**

- A monthly check on proper function for all other autoclaves used to decontaminate waste

b. When the heat-resistant bacterial spores *(Geobacillus stearothermophilus)* in the BI vial are killed, definitive verification for decontamination was achieved by the autoclave.

c. Each specific cycle (type, time, temperature, etc.) used to decontaminate biohazardous waste must be verified with B.I. testing.

d. Label the BI with pertinent information (date, autoclave tested, location in chamber, etc.)

e. Place BI in the waste load in one of the following ways:
- Challenge test packs are placed with a waste load (such as between 2 bags of waste).
- BI vials (no packs) are positioned <u>within</u> a load, such as inside a Sharps container or bag of waste, to encounter the greatest challenge to steam penetration.
- For more thorough testing, additional vials can be placed in critical loads.

d. BI vials used alone can be taped to the same extenders used for CI strips to facilitate placement and avoid direct exposure to waste.

e. Upon completion of the cycle, follow BI manufacturer's instructions for activating and incubating test vials and positive control. Observe vials at specified intervals (such as 24 to 48 hours) for a color change indicating bacterial growth. If growth occurs, the autoclave tested has not met appropriate operating parameters.

f. Results must be recorded on the Biological Indicator Testing log.

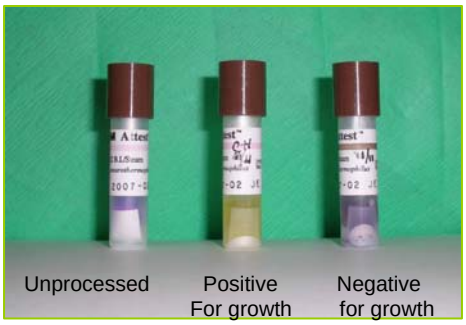
g. See the EHSS website to download SOP for Biological Indicators (BI).

<u>g.</u> <u>BI Failures:</u>

- All BI testing failures must be reported immediately to the technician responsible for the autoclave, who will investigate and take corrective action.
- Users of the autoclave also must be informed of any failure that may have affected runs processed in the autoclave at or near the time of testing.

☑ **B.I. INCUBATOR**

BI TEST RESULTS



☑ **RECORD IN BI STERILITY TESTING LOG**

- The autoclave in question must be taken out of service for decontamination of waste until the problem is found and proper function is restored as verified by repeat BI testing.

h. BI verification testing should also be performed:

- After a sterilizer has been repaired
- As required for research needs

☑ **SIGN ON OUT-OF-SERVICE AUTOCLAVE**

11. Keep autoclaves in good repair with preventive maintenance.

a. The responsible technician, the autoclave's manufacturer, or the autoclave's sales /service representative can provide more information.

b. If you suspect there is a problem with your autoclave's performance, contact the responsible technician for assistance.

☑ **UTILITIES SIDE OF AUTOCLAVE**

References

1. Le, R.N., et al (2005), Autoclave Testing in a University Setting. *Applied Biosafety*, 10(4), 248-252.

2. Centers for Disease Control and Prevention, Oral Health Resources "Sterilization – Monitoring FAQs," April 2005. www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization_monitoring.htm

3. University of Ottawa Environmental Health and Safety Service, A Guideline for the Safe Use of Autoclaves, 9 July 2003, http://www.uottawa.ca/services/ehss/docs/autoclave.pdf

4. 3M™ Technical Information Sheet: 3M™ Comply ™ (SteriGage™ Steam Chemical Integrator, 1999, 70-2009-0710-6 (29.5) DPI

5. 3M™ Technical Product Profile: 3M™ ATTEST™ Biological Monitoring System, 1994

AUTOCLAVE LOG

Autoclave Type: _____ Lab Used for Spore Test: _____

Date of Run	Load # (Sequential)	Temperature (degree F)	Steam Pressure Reading	Time Sterilized (Minutes)	Spore Test results reviewed and filed (Date)	Cleaned Weekly) (Clean chamber and trays per manufacturer guidelines)	Name of Staff Completing tasks (Full name and title)

Problem Resolution

Date	Problem	How Handled	Name of Staff/Signature

AUTOCLAVE CLEANING LOG

Initial and Date Upon Completion of Task

DAILY (Cleaning external surfaces and clean sterilizer door gasket per Manufacturer Guidelines)					WEEKLY (Cleaning chamber and trays per Manufacturer Guidelines)	MONTHLY (Flush system and clean chamber filter per Manufacturer Guidelines)
Monday	Tuesday	Wednesday	Thursday	Friday		

Initial _____ Print name of person checking _____

Initial _____ Print name of person checking _____

Initial _____ Print name of person checking _____

AUTOCLAVE CLEANING LOG

Initial and Date Upon Completion of Task

DAILY (Cleaning external surfaces and clean sterilizer door gasket per Manufacturer Guidelines)					WEEKLY (Cleaning chamber and trays per Manufacturer Guidelines)	MONTHLY (Flush system and clean chamber filter per Manufacturer Guidelines)
Monday	Tuesday	Wednesday	Thursday	Friday		
				7/1/22 JD	7/1/22 JD	7/1/22 JD
7/4/22 -Holiday	7/5/22 JD	Closed	7/7/22 JD	7/8/22 JD	7/8/22 JD	

SAMPLE

JD
Initial

JOHN DOE
Print name of person checking

Initial

Print name of person checking

SECTION	Approval date:	
Infection Control	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Instrument Sterilization	**Revision date:**	

POLICY:

This site will ensure that all reusable medical instruments are properly sterilized after each use.

PROCEDURE:

I. CLEANING PRIOR TO STERILIZATION

Prior to undergoing the sterilization process, soiled instruments/equipment are thoroughly cleaned, rinsed, dried, and inspected for the presence of dried blood or other debris. Trained personnel will be able to demonstrate or verbally explain procedure(s) used for cleaning prior to sterilization, according to site-specific policy and/or manufacturer/product label directions.

II. COLD CHEMICAL STERILIZATION

The use of liquid cold chemical sterilants shall be restricted to reprocessing devices that are heat-sensitive and incompatible with other sterilization methods. All other items should be heat sterilized (using an autoclave) or disposable. 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 exposure times and solution expiration date/time is communicated to staff. Written site-specific policy/procedures or Manufacturer's Instructions for cold sterilization are available on site for staff reference.

The OSHA Hazard Communication Standard requires manufacturers and importers of hazardous chemicals to develop Material Safety Data Sheets (MSDS) for each chemical or mixture of chemicals. MSDS for cold chemical sterilants shall be readily available on site to staff who work with the products to which they could be exposed. Staff shall attend training classes in safety awareness about the use and exposure to cold chemical sterilants used on site. Personnel are familiar with and is able to recognize signs and symptoms of exposure to cold chemical sterilants used on site. Staff shall be aware of the procedures and are able to perform the appropriate clean up in the event of spillage. The appropriate PPE for cold chemical sterilant clean-up shall be readily available.

III. AUTOCLAVE/STEAM STERILIZATION

The 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. If instruments/equipment are transported off-site for sterilization, equipment-handling and transport procedures are available on site to staff.

IV. AUTOCLAVE MAINTENANCE

A. The autoclave is maintained and serviced according to manufacturer's guidelines. The autoclave is serviced annually by a qualified technician, if the manufacturer's guidelines are not available. A dated sticker indicating the maintenance date will be placed on the autoclave or a service receipt will be kept on file to indicate documentation of mechanical problems, result/outcome of routine servicing, calibration, and repairs.

B. An autoclave instrument sterilization log shall be kept on file and shall include the following:
   - Date
   - Time
   - Duration of run cycle
   - Temperature
   - Steam pressure
   - Load identification information
   - Operator of each run

V. SPORE TESTING

A. Autoclave spore testing is performed *at least monthly*, unless otherwise stated in the manufacturer's guidelines. Spore testing reports shall be maintained on file and shall include the following:
   - Date
   - Results
   - Types of spore test used
   - Person performing/documentation test results

B. For positive spore tests, the autoclave is removed from service immediately until inspection is completed and a negative retest occurs. The following procedures shall be followed with a positive spore test:
   1. **Report** problem to Office Manager or Doctor
   2. **Repair** autoclave
   3. **Retrieve** all instruments sterilized since last negative spore test
   4. **Re-test** autoclave
   5. **Re-sterilize** retrieved instruments

VI. STERILE PACKAGES

A. Storage areas for sterilized packages are maintained clean, dry, and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer).

B. Sterilized package labels include:
   - Date of sterilization
   - Load run identification information
   - 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
   - Identity (initials or signature) of staff member who sterilized the instruments

C. Maintenance of sterility is event related, not time related. Sterilized items are considered sterile until use, unless an even causes contamination. Sterilized items are not considered sterile if package is opened, wet/moist, discolored, or damaged. Compromised packages shall be removed from sterile package storage area and immediately, repackaged, relabled and resterilized.

D. This site's process for routine evaluation of the integrity and condition of sterilized packages is as follows:

   ☐ Monthly inspection of sterile packages by assigned personnel

   ☐ Other: _____