FACILITY SITE REVIEW

BINDER

SAN FRANCISCO HEALTH PLAN

Here for you

www.sfhp.org/providers/facility-site-review/

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Facility Site Review Binder

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Physical Environment			Notes
☐		Clearly marked (blue) curb or sign designating disabled-parking space near accessible primary entrance.	
☐		Pedestrian ramps have a level landing at the top and bottom of the ramp.	
☐		Exit and exam room doorway openings allow for clear passage of a person in a wheelchair.	
☐		Accessible passenger elevator or reasonable alternative for multi-level floor accommodation.	
☐		Clear floor space for wheelchair in waiting area and exam room.	
☐		Wheelchair accessible restroom facilities.	
☐		Wheelchair accessible handwashing facilities or reasonable alternative.	
☐		All patient areas including floor/carpet, walls, and furniture are neat, clean, and well maintained.	
☐		Restrooms are clean and contain appropriate sanitary supplies.	
☐		Lighting is adequate in all areas to ensure safety.	
☐		**Exit doors and aisles are unobstructed and egress (escape) accessible.**	
☐		Exit doors are clearly marked with “Exit” signs.	
☐		Clearly diagramed “Evacuation Routes” for emergencies are posted in a visible location at all elevators, stairs and exits.	
☐		Electrical cords and outlets are in good working condition.	
☐		Fire Fighting Equipment in accessible location.	
Office Practices: Front Desk			**Notes**
☐		Emergency phone number contacts are posted, updated annually and as changes occur.	
☐		Clinic office hours are posted or readily available upon request.	
☐		Provider office hour schedules are available to staff.	
☐		Arrangement/schedule for after-hours, on-call, supervisory back-up physician coverage is available to site staff.	
☐		Contact information for off-site physician(s) is available at all times during office hours.	
☐		Routine, urgent, and after-hours emergency care instructions/telephone information is made available to patients.	
☐		Appropriate personnel handle emergent, urgent, and medical advice telephone calls.	

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☐		Telephone answering machine, voice mail system, or answering service is used whenever office staff does not directly answer phone calls.	
☐		Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated.	
☐		Appointments are scheduled according to patients' stated clinical needs within the timeliness standards established for Plan members.	
☐		Patients are notified of scheduled routine and/or preventive screening appointments.	
☐		There is a process in place verifying follow-up on missed and canceled appointments.	
☐		Phone number(s) for filing grievances/complaints are located on site.	
☐		Complaint forms and a copy of the grievance procedure are available on site.	
☐		Medical records are readily retrievable for scheduled patient encounters.	
☐		Notification is provided to each member that the MD(s) is licensed and regulated by the Medical Board, and that the Physcian Assistant(s) is licensed and regulated by the Physician Assistant Committee.	
Office Practices: Policy & Procedures			**Notes**
☐		Site has a procedure in place for confirming correct patient/medication/vaccine dosage prior to administration.	
☐		Interpreter services are made available in identified threshold languages specified for location of site.	
☐		**Office practice procedures allow timely provision and tracking of: Processing internal and external referrals, consultant reports, and diagnostic test results.**	
☐		Office practice procedures allow timely provision and tracking of: Physician Review and follow-up of referral/consultation reports and diagnostic test results.	
☐		Medical documents are filed in a timely manner to ensure availability for patient encounters.	
☐		Medical record release procedures are compliant with State and federal guidelines.	
☐		Storage and transmittal of medical records preserves confidentiality and security.	
☐		Medical records are retained for a minimum of 10 years.	
☐		Current Vaccine Information Sheets (VIS) for distribution to patients are present on site.	
☐		Site utilizes California Immunization Registry (CAIR) or the most current version.	
Staff Preparedness			**Notes**

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☐	✎	All required Professional Licenses and Certifications, issued from the appropriate licensing/certification agency, are current.	
☐	✎	Health care personnel wear identification badges/tags printed with name and title.	
☐		Only qualified/trained personnel operate medical equipment.	
☐	✎	Standardized Procedures provided for Nurse Practitioners (NP) and/or Certified Nurse Midwives (CNM).	
☐	✎	A Practice Agreement defines the scope of services provided by Physician Assistants (PA) and Supervisory Guidelines define the method of supervision by the Supervising Physician.	
☐	✎	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.	
☐		Each NPMP that prescribes controlled substances has a valid Drug Enforcement Administration Registration Number.	
☐	✎	The designated supervising physician(s) on site: Ratio to number of NPMPs does not exceed established ratios in any combination. a) 1:4 NPs b) 1:4 CNMs c) 1:4 PAs d) 1:4 LMs	
☐		The designated supervising physician(s) on site: 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.	
☐		The designated supervising physician(s) on site: Evidence of NPMP supervision.	
☐		Persons providing language interpreter services, including sign language on site, are trained in medical interpretation.	
Staff Preparedness: Training			**Notes**
☐	✎	There is evidence staff has received safety training and/or has safety information available on the following: Fire safety and prevention.	
☐	✎	There is evidence staff has received safety training and/or has safety information available on the following: Emergency non-medical procedures (e.g. site evacuation, workplace violence).	
☐	✎	Documentation of education/training for non-licensed medical personnel is maintained on site.	
☐	✎	Annual Training: Infection Control/Universal Precautions	
☐	✎	Annual Training: Blood Borne Pathogens Exposure Prevention	

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☐		Annual Training: Biohazardous Waste Handling	
☐		Training: Patient confidentiality	
☐		Training: Informed Consent, including human sterilization	
☐		Training: Prior Authorization requests	
☐		Training: Grievance/Complaint Procedure	
☐		Training: Child/Elder/Domestic Violence Abuse	
☐		Training: Sensitive Services/Minor's Rights	
☐		Training: Health Plan referral process/procedures/resources	
☐		Training: Cultural and linguistics	
☐		Training: Disability Rights and Provider Obligations	
Emergency Planning			**Notes**
☐		An employee alarm system.	
☐		Personnel are trained in procedures/action plan to be carried out in case of medical emergency site.	
☐		Emergency equipment is stored together in easily accessible location and is ready to be used.	
☐		**Emergency medical equipment appropriate to practice/patient population is available on site: Airway management: oxygen delivery system, nasal cannula or mask, bulb syringe and Ambu bag.**	
☐		**Emergency medical equipment appropriate to practice/patient population is available on site: Emergency medicine such as asthma, chest pain, hypoglycemia and anaphylactic reaction management: 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.**	
☐		Emergency medical equipment appropriate to practice/patient population is available on site: Medication dosage chart for all medications included with emergency equipment (or other method for determining dosage) is kept with emergency medications.	
☐		Document checking of emergency equipment/supplies for expiration and operating status at least monthly.	
☐		Replace/re-stock emergency medication, equipment and supplies immediately after use.	
☐		Has a written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer	

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Drugs & Medical Supplies			Notes
☐		**Only qualified/trained personnel retrieve, prepare or administer medications.**	
☐		Drugs are stored in specifically designated cupboards, cabinets, closets or drawers.	
☐		Prescription drug samples, and over-the-counter drugs, hypodermic needles/syringes, all medical sharp instruments, hazardous substances, and prescription pads are securely stored in a lockable space (cabinet or room) within the office/clinic.	
☐		Controlled drugs are stored in a locked space accessible only to authorized personnel.	
☐	✎	A dose-by-dose controlled substance distribution log is maintained.	
☐	✎	Written site-specific policy/procedure for dispensing of sample drugs are available on site.	
☐		Drugs are prepared in a clean area or "designated clean" area if prepared in a multi-purpose room.	
☐		Drugs for external use are stored separately from drugs for internal use.	
☐		Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.	
☐	✎	Refrigerator thermometer temperature is 36º-46º Fahrenheit or 2º-8º Centigrade (at time of site visit).	
☐	✎	Freezer thermometer temperature is 5º Fahrenheit or –15º Centigrade, or lower (at time of site visit).	
☐		Site utilizes drugs/vaccine storage units that are able to maintain required temperature	
☐	✎	Daily temperature readings of drugs/vaccines refrigerator and freezer are documented.	
☐		Drugs and vaccines are stored separately from test reagents, germicides, disinfectants, and other household substances.	
☐		There are no expired drugs on site.	
☐	✎	Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas.	
☐		All stored and dispensed prescription drugs are appropriately labeled.	
☐		**Only lawfully authorized persons dispense drugs to patients.**	
☐		**Drugs and Vaccines are prepared and drawn only prior to administration.**	
Exam Room			**Notes**
☐		Exam rooms and dressing areas safeguard patients' right to privacy.	
☐		Procedures are followed to maintain the confidentiality of personal patient information.	
☐	✎	Hazardous substances are appropriately labeled.	
☐		Exam tables and lights are in good repair.	

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☐		Stethoscope and sphygmomanometer with various size cuffs (e.g. child, adult, obese/thigh).	
☐		Thermometer with a numeric reading.	
☐		Basic exam equipment: percussion hammer, tongue blades, patient gowns.	
☐		Scales: standing balance beam and infant scales.	
☐		Measuring devices for stature (height/length) measurement and head circumference measurement.	
☐		Eye charts (literate and illiterate) and occluder for vision testing.	
☐		Ophthalmoscope.	
☐		Otoscope with multi-size ear speculums appropriate to the population served.	
☐		A pure tone, air conduction audiometer is located in a quiet location for testing.	
☐		Soap or antiseptic hand cleaner and running water are available in exam and/or treatment areas for hand washing.	
☐		A waste disposal container is available in exam rooms, procedure/treatment rooms, and restrooms.	
☐		Biohazardous (non-sharp) wastes are contained separate from other trash/waste.	
☐		Disinfectant solutions used on site are: Approved by the Environmental Protection Agency (EPA).	
☐		Disinfectant solutions used on site are: Effective in killing HIV/HBV/TB.	
☐		Disinfectant solutions used on site are: Follow manufacturer instructions.	
Laboratory			**Notes**
☐		Medical equipment is clean.	
☐		Written documentation demonstrates the appropriate maintenance of all medical equipment according to equipment manufacturer's guidelines.	
☐		Laboratory test procedures are performed according to current site-specific CLIA certificate.	
☐		Testing personnel performing clinical lab procedures have been trained.	
☐		Lab supplies (e.g. vacutainers, vacutainer tubes, culture swabs, test solutions) are inaccessible to unauthorized persons.	
☐		Lab test supplies are not expired.	
☐		Site has a procedure to check expiration date and a method to dispose of expired lab test supplies.	
☐		Written site-specific policy/procedures or manufacturer's instructions for instrument/equipment sterilization are available to staff.	

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☐		Staff adheres to site-specific policy and/or manufacturer/product label directions for the following procedures: Cleaning reusable instruments/equipment prior to sterilization.	
Pharmacy			**Notes**
☐		If there is a pharmacy on site, it is licensed by the CA State Board of Pharmacy.	
Radiology			**Notes**
☐		Site has current CA Radiologic Health Branch Inspection Report or Proof of Registration if there is radiological equipment on site.	
☐		Current copy of Title 17 with a posted notice about availability of Title 17 and its location.	
☐		"Radiation Safety Operating Procedures" posted in highly visible location.	
☐		"Notice to Employees Poster" posted in highly visible location.	
☐		"Caution, X-ray" sign posted on or next to door of each room that has X-ray equipment.	
☐		Physician Supervisor/Operator certificate posted and within current expiration date.	
☐		Technologist certificate posted and within current expiration date.	
☐		Operator protection devices: radiological equipment operator must use lead apron or lead shield.	
☐		Gonadal shield (0.5 mm or greater lead equivalent): for patient procedures in which gonads are in direct beam.	
Infection Control			**Notes**
☐		**Blood, other potentially infectious materials, and Regulated Wastes are placed in appropriate leak proof, labeled containers for collection, handling, processing, storage, transport, or shipping.**	
☐		**Needlestick safety precautions are practiced on site.**	
☐		All sharp injury incidents are documented.	
☐		Storage areas for regulated medical wastes are maintained secure and inaccessible to unauthorized persons.	
☐		Contaminated laundry is laundered at the workplace or by a commercial laundry service.	
☐		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).	
☐		Equipment and work surfaces are appropriately cleaned and decontaminated after contact with blood or other potentially infectious material.	

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☐		Routine cleaning and decontamination of equipment/work surfaces is completed according to site-specific written schedule.	
☐		**Cold chemical sterilization/high level disinfection: Staff demonstrate /verbalize necessary steps/process to ensure sterility and/or high-level disinfection to ensure sterility/disinfection of equipment.**	
☐		Cold chemical sterilization/high level disinfection: Confirmation from manufacturer item(s) is/are heat sensitive.	
☐		**Cold chemical sterilization/high level disinfection: Appropriate PPE is available, exposure control plan, Material Safety Data Sheets and clean up instructions in the event of a cold chemical sterilant spill.**	
☐		Staff demonstrate/verbalize necessary steps/process to ensure sterility.	
☐		Autoclave maintenance per manufacturer's guidelines.	
☐		**Spore testing of autoclave/steam sterilizer with documented results (at least monthly).**	
☐		**Management of positive mechanical, chemical, and/or biological indicators of the sterilization process.**	
☐		Sterilized packages are labeled with sterilization date and load identification information.	
☐		Storage of sterilized packages.	
☐		Site has method(s) in place for drug and hazardous substance disposal.	
☐		Site has procedure for effectively isolating infectious patients with potential communicable conditions.	
☐		**Personal Protective Equipment (PPE) for Standard Precautions is readily available for staff use.**	
Health Education			**Notes**
☐		Health education materials and Plan-specific resource information are: Readily accessible on site or are made available upon request.	
☐		Health education materials and Plan-specific resource information are: Applicable to the practice and population served on site.	
☐		Health education materials and Plan-specific resource information are: Available in threshold languages identified for county and/or area of site location.	

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Format Criteria			Notes
☐		Member identification is on each page.	
☐		Individual personal biographical information is documented.	
☐		Emergency "contact" is identified.	
☐		Medical records are maintained and organized.	
☐		Member's assigned and/or rendering primary care physician (PCP) is identified.	
☐		Primary language and linguistic service needs of non-or limited-English proficient (LEP) or hearing/speech-impaired persons are prominently noted.	
☐		Person or entity providing medical interpretation is identified.	
☐		Signed Copy of the Notice of Privacy.	
Documentation Criteria			**Notes**
☐		Allergies are prominently noted.	
☐		Chronic problems and/or significant conditions are listed.	
☐		Current *continuous* medications are listed	
Appropriate consents are present			
☐		Release of Medical Records	
☐		Informed Consent for invasive procedures	
☐		Advance Health Care Directive Information is offered	
☐		All entries are signed, dated and legible.	
☐		Errors are corrected according to legal medical documentation standards.	
Coordination of Care Criteria			**Notes**
☐		History of present illness or reason for visit is documented.	
☐		Working diagnoses are consistent with findings.	
☐		Treatment plans are consistent with diagnoses.	
☐		Instruction for follow-up care is documented.	
☐		Unresolved/continuing problems are addressed in subsequent visit(s).	
☐		There is evidence of practitioner review of consult/referral reports and diagnostic test results.	
☐		There is evidence of follow-up of specialty referrals made, and results/reports of diagnostic tests, when appropriate.	

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☐		Missed primary care appointments and outreach efforts/follow-up contacts are documented.	
Pediatric Preventive Criteria			**Notes**
☐		Comprehensive History and Physical	
☐		IHEBA	
☐		Comprehensive History and Physical exam completed at age appropriate frequency	
☐		Subsequent Periodic IHEBA	
Well-child Visit			
☐		Alcohol Disorder: Screening and Behavioral Counseling	
☐		Anemia Screening	
☐		Anthropometric Measurements	
☐		Anticipatory Guidance	
☐		Autism Spectrum Disorder Screening	
☐		Blood Lead Screening	
☐		Blood Pressure Screening	
☐		Dental/Oral Health Assessment	
☐		Fluoride Supplementation	
☐		Fluoride Varnish	
☐		Depression Screening	
☐		Suicide-Risk Screening*	
☐		Maternal Depression Screening	
☐		Developmental Disorder Screening	
☐		Developmental Surveillance	
☐		Drug Disorder: Screening and Behavioral Counseling	
☐		Dyslipidemia Screening	
☐		Hearing Screening	
☐		Hepatitis B Virus Screening	
☐		Hepatitis C Virus Screening	
☐		Human Immunodeficiency Virus (HIV) Infection Screening	

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☐		Psychosocial/Behavioral Assessment	
☐		Sexually Transmitted Infections (STIs) Screening and Counseling	
☐		Sudden Cardiac Arrest and Sudden Cardiac Death Screening*	
☐		Tobacco Use Screening, Prevention, and Cessation Services	
☐		Tuberculosis Screening	
☐		Vision Screening	
Childhood Immunizations			
☐		Given according to Advisory Committee on Immunization Practices (ACIP) guidelines	
☐		Vaccine administration documentation	
☐		Vaccine Information Statement (VIS) documentation	
Adult Preventive Criteria			**Notes**
Initial Health Assessment (IHA): Includes H&P and Individual Health Education Behavioral Assessment (IHEBA)			
☐		Comprehensive History and Physical	
☐		IHEBA	
Periodic Health Evaluation according to most recent United States Preventive Services Taskforce (USPSTF) Guidelines			
☐		Comprehensive History and Physical Exam completed at age-appropriate frequency	
☐		Subsequent Periodic IHEBA	
Adult Preventive Care Screenings			
☐		Abdominal Aneurysm Screening	
☐		Alcohol Use Disorder Screening and Behavioral Counseling	
☐		Breast Cancer Screening	
☐		Cervical Cancer Screening	
☐		Colorectal Cancer Screening	
☐		Depression Screening	
☐		Diabetic Screening	
☐		Comprehensive Diabetic Care	
☐		Drug Disorder Screening	

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☐		Behavioral Counselling	
☐		Dyslipidemia Screening	
☐		Folic Acid Supplementation	
☐		Hepatitis B Virus Screening	
☐		Hepatitis C Virus Screening	
☐		High Blood Pressure Screening	
☐		HIV Screening	
☐		Intimate Partner Violence Screening for Women of Reproductive Age	
☐		Lung Cancer Screening	
☐		Obesity Screening and Counseling	
☐		Osteoporosis Screening	
☐		Sexually Transmitted Infection (STI) Screening and Counseling	
☐		Skin cancer Behavioral Counseling	
☐		Tobacco Use Screening	
☐		Counselling and Intervention	
☐		Tuberculosis Screening	
Adult Immunizations			
☐		Given according to ACIP guidelines	
☐		Vaccine administration documentation	
☐		Vaccine Information Statement (VIS) documentation	
OB/CPSP Preventive Criteria			**Notes**
		Initial Comprehensive Prenatal Assessment (ICA)	
☐		Initial prenatal visit	
☐		Obstetrical and Medical History	
☐		Physical Exam	
☐		Dental Assessment	
☐		Healthy weight gain and behavior counseling	
Lab Tests			

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☐		Bacteriuria Screening	
☐		Rh Incompatibility Screening	
☐		Diabetes Screening	
☐		Hepatitis B Virus Screening	
☐		Hepatitis C Virus Screening	
☐		Chlamydia Infection Screening	
☐		Syphilis Infection Screening	
☐		Gonorrhea Infection Screening	
☐		Human Immunodeficiency Virus (HIV) Screening	
First Trimester Comprehensive Assessment			
☐		Individualized Care Plan (ICP)	
☐		Nutrition Assessment	
Psychosocial Assessment			
☐	📝	Maternal Mental Health Screening	
☐		Social Needs Assessment	
☐		Substance Use/Abuse Assessment	
☐		Breast Feeding and other Health Education Assessment	
☐		Preeclampsia Screening	
☐		Intimate Partner Violence Screening	
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☐		ICP	
☐		Nutrition Assessment	
Psychosocial Assessment			
☐	📝	Maternal Mental Health Screening	
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☐		Breast Feeding and other Health Education Assessment	
☐		Preeclampsia Screening	

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☐		Low Dose Aspirin	
☐		Intimate Partner Violence Screening	
☐		Diabetes Screening	
Third Trimester Comprehensive Assessment			
☐		ICP Update and Follow Up	
☐		Nutrition Assessment	
Psychosocial Assessment			
☐		Maternal Mental Health Screening	
☐		Social Needs Assessment	
☐		Substance Use Disorder Assessment	
☐		Breastfeeding and other Health Education Assessment	
☐		Preeclampsia Screening	
☐		Low Dose Aspirin	
☐		Intimate Partner Violence Screening	
☐		Diabetic Screening	
☐		Screening for Strep B	
☐		Screening for Syphilis	
☐		TDAP Immunization	
☐		Prenatal care visit periodicity according to most recent American College of Obstetricians and Gynecologists (ACOG) standards	
☐		Influenza Vaccine	
☐		COVID Vaccine	
☐		Referral to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and assessment of Infant Feeding Status	
☐		HIV-related Services *offered*	
☐		AFP/Genetic Screening offered	
☐		Family Planning Evaluation	
Comprehensive Postpartum Assessment			
☐		ICP	

Medical Record Review Checklist

📝 = Resource available on SFHP.org

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☐		Nutrition Assessment	
Psychosocial Assessment			
☐	📝	Maternal Mental Health Screening/Postpartum Depression Screening	
☐		Social Needs Assessment	
☐	📝	Substance Use Disorder Assessment	
☐		Breastfeeding and other Health Education Assessment	
☐		Comprehensive Physical Exam	

FSR-C Checklist

Question Number	Accessibility Indicator	Critieria Indicator	Description	Explanation, if any
1	P = Parking		Is off-street public parking available? Review any garage or parking lot within 1-2 blocks Please also document if there is a blue curb on the street near the entranceway and if the blue curb has a curb ramp (slope for the wheelchair to get to the sidewalk.	
2	P = Parking		Are accessible parking spaces provided in off-street parking?	
3	P = Parking	Critical	Are the correct number of accessible parking spaces provided?	
4	P = Parking		Is the accessible parking space(s) closest to the main entrance?	
5	P = Parking		Is there an access aisle next to the accessible space(s)?	
6	P = Parking		Is the parking space(s) and access aisle(s) free of curb ramps that extend into the space and other obstructions?	
7	P = Parking	Critical Element	Do curbs on the route from off-street public parking have curb ramps at the off street garage or lot parking locations?	
8	P = Parking	Critical	Do curbs on the route from off-street public parking have curb ramps at the drop off locations?	
9	P = Parking		Does every accessible parking space have a vertical sign posted with the International Symbol of Accessibility?	
10	P = Parking		Are signs mounted a minimum of 60 inches above the ground surface so that they can be seen over a parked vehicle? The bottom of the signs must be at least 60” from the ground surface.	
11	P = Parking	Critical	Is VAN accessible parking provided?	
12	P = Parking		Is VAN accessible parking signage provided?	
13	P = Parking		If van accessible parking is provided in a parking garage, is there at least 8 feet 2 inches (98 inches total) vertical clearance available for full-sized, lift equipped vans?	
14	EB = Exterior Building	Critical Element	For exterior routes, if the accessible route crosses a curb, is a curb ramp provided to the building entrance from the following: (Please mark NA for those that do not apply.) a. Parking (from the accessible garage or parking lot)? b. Public transportation (Muni)? c. Public sidewalk (drop-offs and neighborhood sidewalks)?	
15	EB = Exterior Building		Is the accessible route to the building entrance at least 36 inches wide for exterior routes from the following: (Please mark NA for those that do not apply.) a. Parking? b. Public transportation? c. Public sidewalk?	
16	EB = Exterior Building		Is the accessible route to the building entrance stable, firm, and slip resistant from the following: (Please mark NA for those that do not apply.) a. Parking? b. Public transportation? c. Public sidewalk?	
17	EB = Exterior Building		Is there an accessible route that does not include stairs or steps?	
18	EB = Exterior Building		Is the route to the entrance from the accessible parking spaces, including transitions at curb ramps, free of grates, gaps, and openings that are both greater than ½ inch wide and over ¼ inch deep?	
19	EB = Exterior Building		Is an access ramp present?	If there is more than one ramp, select the one that appears to be the primary access ramp.
20	EB = Exterior Building	Critical	Is each run (leg) of the ramp no longer than 30 feet between landings?	Total length of the ramp
21	EB = Exterior Building		Are 60 inches (5 feet) long, level landings provided at the top and bottom of each ramp run?	
22	EB = Exterior Building	Critical Element	Are handrails provided on both sides of the ramp that are mounted between 34 and 38 inches above the ramp surface, if it is longer than 6 feet?	
23	EB = Exterior Building	Critical	Are all ramps at least 36 inches wide?	
24	EB = Exterior Building		Is the main entrance accessible?	

25	EB = Exterior Building	Critical	If a main entrance is not accessible (steps or too long a ramp), is there another accessible entrance?	

Question Number	Accessibility Indicator	Critieria Indicator	Description	Explanation, if any
26	EB = Exterior Building		If a main entrance is not accessible, is there directional signage indicating the location of the accessible entrance?	
27	EB = Exterior Building	Critical Element	Do doors have an opening at least 32 inches wide (at the narrowest point below the opening hardware) when opened to 90°?	
28	EB = Exterior Building	Critical	Is space available for a wheelchair user to approach, maneuver, and open the door?	
29	EB = Exterior Building		Is the space required to open the door level and clear of movable objects (chairs, trash cans, etc.)?	
30	EB = Exterior Building		Are there automatic doors?	Document if doors have touch pads and/or have sensors, so they open automatically
31	EB = Exterior Building	Critical	Do entrance doors have handles that can be opened without grasping, pinching, or twisting of the wrist?	
32	IB = Interior Building		Is there an interior route to the medical office?	There is an interior route if the front door does not open directly into the office or clinic lobby.
33	IB = Interior Building		Is there an interior accessible route to the medical office that does not include stairs or steps?	
34	IB = Interior Building	Critical	Are ALL interior paths of travel at least 36 inches wide?	
35	IB = Interior Building		Is the interior accessible route stable, firm, and slip resistant?	
36	IB = Interior Building		Is the interior accessible route well lighted?	
37	IB = Interior Building	Critical	If there are stairs on the accessible route, are there handrails on each side?	
38	IB = Interior Building		If there are stairs, are all stairs risers closed that are on the accessible route?	
39	IB = Interior Building		If there are stairs, are all stair treads marked by a stripe providing a clear visual contrast to assist people with visual impairments?	
40	IB = Interior Building	If lift, Critical Element	If a platform lift is used, can it be used without assistance?	A platform lift is any apparatus that will take a wheelchair or scooter to an accessible route into the clinic.
41	IB = Interior Building		Does the interior door to the medical office require less than 5 pounds of pressure to open?	Doors opening into major corridors are usually fire doors
42	IB = Interior Building		Is there a clear space 30 inches wide by 48 inches long in the waiting area(s) for a wheelchair or scooter user to park that is not in the path of travel?	
43	IB = Interior Building		Is the path through the medical office free of any objects that stick out into the circulation path that a blind person might not detect with a cane?	Guideline: No answer if there is any object that protrudes more than 4 inches and is located between 27 -80 inches from the floor
44	IB = Interior Building		If floor mats are used, are the edges of floor mats stiff enough or secured so that they do not roll up?	
45	IB = Interior Building		Is a section of the sign-in/registration counter no more than 34 inches high and at least 36 inches wide and free of stored items.	
46	IB = Interior Building		Does the office have a method, other than a lowered counter, by which people can sign in/register? (If yes, please note this method in comments.)	This question should be answered for every office, even if there is a counter at the right height.
47	IB = Interior Building		Do signs identifying permanent rooms and spaces include raised letters and Braille?	If no signs, this is an NA
48	IB = Interior Building		Are the raised letters and Braille signs mounted between 48 inches and 60 inches from the floor?	If no signs, this is an NA
49	IB = Interior Building		If the building has a fire alarm system, are visual signals provided in each public space, including toilet rooms and each room where patients are seen?	Make sure that they are red with clear lights; other lights are security or generator powered lights when the power goes out.
50	IB = Interior Building		Are all patient-operated controls (call buttons, self-service literature, brochures, hand sanitizers, etc.) mounted or presented between 15 inches and 48 inches from the floor?	
51	IB = Interior Building		Are all patient operated controls (e.g., call buttons, hand sanitizers) operable with one hand without grasping, pinching, or twisting to operate?	This seems not to include door knobs.
52	IB = Interior Building		Is there an elevator?	
53	IB = Interior Building	If elevator, Critical	If needed, is the elevator available for public/patient use during business hours?	

Question Number	Accessibility Indicator	Critieria Indicator	Description	Explanation, if any
54	IB = Interior Building	If elevator, Critical	Is the elevator equipped with both visible and audible door opening/closing and floor indicators?	Listen for dings on every floor or audible voice saying what floor you are on.
55	IB = Interior Building	If elevator, Critical	Is there a raised letter and Braille sign on each side of each elevator jamb?	
56	IB = Interior Building	If elevator, Critical	Are the hall call buttons for the elevator no higher than 48 inches from the floor?	
57	IB = Interior Building	If elevator, Critical Element	Is the elevator car large enough for a wheelchair or scooter user to enter, turn to reach the controls, and exit?	If door is not 36" wide, the response is a "no" Elevator door opens in the: center or side?
58	IB = Interior Building	If elevator, Critical	Do the buttons on the control panel inside the elevator have Braille and raised characters/symbols near the buttons?	
59	IB = Interior Building		Is there an emergency communication system in the elevator?	
60	R = Restroom		Is the elevator emergency communication system usable without requiring voice communication?	
61	R = Restroom		Do raised letters and Braille identify the emergency intercom in the elevator?	Emergency intercom can be a phone or speaker system (look for speaker box/holes)
62	R = Restroom		Is there an accessible toilet room?	
63	R = Restroom		If there is an inaccessible toilet room, is there directional signage to an accessible toilet room?	
64	R = Restroom		Does the interior door to the restroom require less than 5 pounds of pressure to open?	
65	R = Restroom	Critical Element	For all toilet rooms with and without stalls: Are grab bars provided, one on the wall behind the toilet and one on the wall next to the toilet?	Grab bars should be installed in a horizontal position between 33 and 36 inches above the floor measured to the top of the gripping surface.
66	R = Restroom		Are all objects mounted at least 12 inches above and 1½ inches below the grab bars?	
67	R = Restroom	Critical Element	Is the toilet paper dispenser mounted below the side grab bar 12 inches or less from the front of the toilet, 36 inches maximum from the rear wall, and at least 19 inches high to the dispensing point?	ADA clarification: Is it mounted below the side grab bar with the centerline of the dispenser between 7 inches and 9 inches in
68	R = Restroom	Critical Element	Is there a space that is at least 30 inches wide and 48 inches deep to allow wheelchair users to park in front of the sink?	Guideline includes 17 in. x 19 in., to the front of the sink from the dip in the sink (in front of the handles) to get a "yes" Document the inches from the back of the wall to the front of the sink, as 36 in. meets
69	R = Restroom		Is the space in front of the sink free of trash cans and other movable items?	
70	R = Restroom		Are the pipes and water supply lines under the sink wrapped with a protective cover?	
71	R = Restroom	Critical Element	Are faucet handles operable with one hand and without grasping, pinching, or twisting? (Check Yes if faucets are automatic.)	A single lever is also a "yes"
72	R = Restroom		Are all dispensers mounted no higher than 40 inches from the floor?	
73	R = Restroom		Are all dispensers (soap, paper towel, etc.) operable with one hand and without grasping, pinching, or twisting?	
74	R = Restroom		If there is a pass-through door for specimen collection, is there a 30 inches by 48 inches space for a wheelchair or scooter user to park in front of it?	
75	R = Restroom	Critical Element	Toilet room without stalls: Do toilet room doorways have a minimum clear opening of 32 inches with the door open at 90 degrees, measured between the face of the door and the opposite stop?	
76	R = Restroom		Is the space inside the toilet room without stalls clear, without trash cans, shelves, equipment, chairs, and other movable objects?	
77	R = Restroom	Critical Element	Toilet Room with stalls: Is there a 60-inch diameter turning circle or a 60 inch x 60 inch "T"-shaped space inside the toilet room with stalls to allow a turn around for wheelchair and scooter users?	
78	R = Restroom		Is toilet room with stall is the space inside the accessible stall clear, without trash cans, shelves, equipment, chairs, and other movable objects?	
79	R = Restroom		Can the hardware on the stall door be operated without grasping, pinching, or twisting of the wrist?	

80	E = Exam Room	Critical Element	Do exam room doorways have a minimum clear opening of 32 inches with the door open at 90 degrees, measured between the face of the door and the opposite stop?	Please document each room; I have made extra pages for documentation. Identify which room # for each room
81	E = Exam Room	Critical Element	Is there a height adjustable exam table that lowers to between 17 inches and 19 inches from the floor to the top of the cushion?	Note: UMF ETs are = 20"; please document but note UMF

Question Number	Accessibility Indicator	Critieria Indicator	Description	Explanation, if any
82	E = Exam Room	Critical Element	Is there space next to the height adjustable exam table for a wheelchair or scooter user to approach, park, and transfer or be assisted to transfer onto the table?	
83	E = Exam Room		Does the exam table provide elements to assist during a transfer (such as rails) and support a person while on the table? (If yes, please list in comments.)	
84	E = Exam Room		Is a lift available to assist staff with transfers (portable, overhead, or ceiling mounted)?	Is there a Hoyer or other type of lift to transfer patients onto their exam tables.
85	E = Exam Room	Critical Element	Is there a 60 inch diameter turning circle or a 60 inch x 60 inch "T"-shaped space so that a wheelchair or scooter user can make a 180° turn?	
86	E = Exam Room	Critical Element	Is a weight scale available within the medical office with a platform to accommodate a wheelchair or scooter and the patient?	Name/model of accessible scale: SFHP is collecting information on offices that have bariatric scales. Does this office have a scale that weights >500 lbs. If yes, what is the model?

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Site Accessibility by Individuals with Physical Disabilities		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

The purpose of the PARS is to assess the physical accessibility of provider sites using a set of standards related to parking, building, elevator, doctor's office, exam room, and restroom.

Definition:

Physical Accessibility Review Survey (PARS)

a. Parking (4 Critical Elements)
b. Exterior Building (8 Critical Elements)
c. Interior Building (3 - 10 Critical Elements)
d. Restroom (6 Critical Elements)
e. Exam Room (2 Critical Elements)
f. Exam Table/Scale (3 Medical Equipment Elements)

Policy:

Site shall be accessible and useable by individuals with physical disabilities. The site will meet city, county and state building structure and access ordinances for persons with physical disabilities.

Purpose:

I. Accommodations

A. The site shall maintain the following safety accommodations for physically disabled persons.

1. Designated disabled parking space near the primary entrance.
    a) Staff will assist disabled members who choose to continue to seek care at the site, in spite inaccessibility.
    b) Staff will discuss the plan with the member prior to a scheduled appointment. A meeting point, as near as possible to an entrance, will be agreed upon.
    c) Staff will meet the member at the scheduled time/place and assist the member as appropriate.
2. Pedestrian ramps will be maintained. (Any path is considered a ramp if the slope is greater than a one foot rise in twenty feet of horizontal run.)
    a) Level landings at the top and bottom of all ramps will be maintained clear of any obstruction. Every staff member is responsible for clearing the landings at any time an obstruction is noted.
3. Exit doorways width (at least 32 inches) will allow for the passage of a wheelchair.
    a) Landings on each side of exit doors and the doorway openings will be maintained clear of any obstruction. Every staff member is responsible for clearing the landings and doorways at any time an obstruction is noted.
4. Passenger elevator will be maintained in working condition for multi-level floor accommodation.
5. A clear floor space will be provided for persons in wheelchairs.
    a) Staff may take the member into the exam room or make adjustments in furniture as required.
6. The restrooms will be accessible to physically disabled individuals
    a) Staff may make a reasonable alternative available to the member, as needed. Alternative may include direct or accompanying the member to a nearby disabled-accessible restroom, physically assisting the member into a smaller restroom, providing a urinal, bedpan, or commode and sanitary supplies per the needs of the member.
7. Hand washing facilities will be available and include running water, soap and paper towels.
    a) Staff may provide a hand sanitizer to the member if the above items are not available/accessible.
8. Interpreter services for the hearing impaired will be provided as needed at no cost to the member.
9. Health education materials are made available to the members in alternative formats; providers can obtain these materials from their contracted health plans Health Education Departments.

II. Changes in Access/Availability

A. Notification

1. If at any time the site becomes inaccessible to physically disabled individuals, all contracted health plans will be notified in writing.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	SF Application Process for (Blue) Curb or Sign Designating Disabled-Parking Space
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or superseding APL
Relevant Law/Standard:	24 CCR (CA Building Standards Code); 28 CFR §35 (American Disabilities Act of 1990, Title II, Title III) All facilities designed, altered, or constructed after January 26, 1992 for the use of public entity must be readily accessible and usable by persons with disabilities.
Agency/Organization Source:	San Francisco Municipal Transportation Agency (SFMTA)
Agency/Organization URL	https://www.sfmta.com/services/new-color-curb

Background:

San Francisco Municipal Transportation Agency (SFMTA) is a department of the City and County of San Francisco responsible for the management of all ground transportation in the city.

Purpose:

A blue zone designates parking spaces for persons with a valid disabled parking permit. Blue zones are normally located in areas with high public use, such as in dense commercial areas, and near public parks and playgrounds, where the blue zones can serve [many] individuals. **Blue zones are not established for a specific individual or a small select group of individuals at a specific location**. There is no fee for establishing blue zones.

Information:

Blue Zones require an SFMTA Board meeting in addition to the Color Curb Hearing. Requestors are notified by mail or email of the hearing date, time, and location. Postings for proposed changes are posted in the vicinity of the proposed zone 10 days before the actual hearing date.

How to Apply:

• Call 311 to submit your application over the phone, or visit www.sfmta.com/NewColorCurb

• There is no application fee for blue zones, which designate parking for persons with disabilities.

• Applications are usually processed within 30 days. The installation of approve zones may take up to 90 days depending on the complexity of the zone. Applications are initiated online at https://sfmta.tfaforms.net/66.

What to Expect:

SFMTA will review your request and determine whether to recommend the new color curb for installation. • If SFMTA recommends installation, a public hearing will be scheduled at City Hall. You will receive notification by mail of the hearing date, time and location, and public notices will be posted in the vicinity of the proposed zone. The SFMTA completes the permitting process and installs the zone as scheduling permits.

Mail or Visit:

Send all correspondence to SFMTA Color Curb Program, 1 South Van Ness Avenue, 7th Floor, San Francisco, CA 94103

Walk-ins are welcome, but to ensure someone is available to meet you when you visit, please email ccp@sfmta.com in advance if possible.

Contact Information:

Color Curb Program

ccp@sfmta.com

415.701.4639

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Fire Safety and Prevention and Emergency Non-Medical Procedures		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL Cal/OSHA Emergency Action Plan standard (§ 3220)		

Purpose:

Employees must know what types of emergencies may occur and what course of action they must take. Make sure all your employees understand the function and elements of your emergency action plan, including types of potential emergencies, reporting procedures, alarm systems, evacuation plans, and shutdown procedures.

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 nonmedical procedures.

Emergency Action Plans must include the following elements:

A. Procedures for reporting a fire or other emergency
B. Procedures for emergency evacuation, including the types of evacuation and exit route assignments
C. Procedures to be followed by employees who remain to operate critical operations before they evacuate
D. Procedures to account for all employees after evacuation
E. An employee alarm system that has a distinctive signal for each purpose and provides warning for necessary emergency action as called for in the emergency action plan. The employee alarm must be capable of being perceived above ambient noise or light levels by all employees in the affected portions of the workplace. Tactile devices may be used to alert those employees who would not otherwise be able to recognize the audible or visual alarm.

F. Training for each employee on the preferred means of reporting emergencies, such as manual pull box alarms, public address systems, radio or telephones. The employer must also designate and train employees to assist in a safe and orderly evacuation of other employees.

G. Emergency telephone numbers which must be posted near telephones, employee notice boards, and other conspicuous locations when telephones serve as a means of reporting emergencies.

H. The name or job title of every employee who may be contacted by employees who need more information about the plan or an explanation of their duties under the plan.

Procedure:

1) Safe Environment
   a) The provider/designee will ensure the following fire and safety precautions:
      (1) Lighting is adequate in all areas
      (2) Exit doors and aisles are unobstructed and egress (escape) accessible
      (3) Exit doors are clearly marked with "Exit" signs
      (4) Clearly diagramed "Evacuation Routes" for emergencies are posted in visible locations
      (5) Electrical cords and outlets are in good working condition
      (6) At least one type of fire-fighting protection equipment is accessible, at all times
      (1) An employee alarm system for more than 10 employees must have a distinct operable alarm signal. Ten or less employees may use direct voice as an acceptable alarm system.
   b) Staff will be responsible to correct any "unsafe" situation, and/or report the situation to the provider/designee who will make/arrange for correction.
2) Information and Training
   a) Fire Safety & Prevention and non-medical emergency information will be available on site. Staff will 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 will be verifiable and may be part of staff education documented in:
      (1) Informal or formal in services
      (2) New staff orientation
      (3) External training courses
   b) Training topics will include:
      (1) Fire safety and prevention procedures including:
         a. Evacuation routes and exits for the exam rooms, office suite and building
         b. Evacuation procedures
         c. Location of fire alarms, extinguishers, sprinklers and smoke detectors
         d. Emergency phone numbers
      (2) Workplace violence procedures including emergency numbers.
      (3) Earthquake emergency plan.
      (4) Terrorist emergency plan.

Attachments:

1) Emergency Fire Plan (Resource)
2) Emergency Personnel Names and Phone Numbers
3) Site Evacuation Plan (Sample)
4) Employee Alarm System
5) Personnel Training Log (Resource)
6) Workplace Violence Protocol (Resource)
7) Emergency Earthquake Plan (Resource)
8) Emergency Terrorist Plan (Resource)

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

Attachment 1: Emergency Fire Plan (Resource)

Policy

All employees shall be familiar with the disaster plans to assist in a safe evacuation in the event of a fire.

The fire safety policy of this office is, in every event of fire or disaster, act in a manner to preserve lives, prevent panic and the spread of fire. All employees must be aware of and receive training regarding:

- Proper fire safety procedures
- Fire exits
- Fire extinguishers (and sprinkler system)
- Fire zones and applicable space requirements
- Staff member requirements and responsibilities
- Steps to take in the event of fire
- Containment of fire and smoke

Staff is not expected to take any actions that may endanger his or her life, but to ensure the safety of patients and staff the office maintains these requirements:

1. All employees will participate in an annual fire extinguisher training class. A record of individual training is to be maintained in _____.

2. Fire drills are conducted by building management at least every _____. Both morning and afternoon shifts will participate in fire drills to ensure:

    a. Sufficient exposure to procedures for responding to fire, including office, and building exits.

    b. Practice to avoid panic under emergency circumstances.

    c. Fire safety education training.

3. The office conducts or arranges for appropriate in-service of office personnel on fire safety and prevention topics.

The steps listed below are followed as quickly as possible in the event there is any uncontrolled flame or smoke in or near the office/building or its perimeter:

1. Alert all people in the office of fire threat and evaluate fire and extent of flames and smoke.

2. Evacuate patients and visitors from the immediate area.

3. Activate fire alarm.

4. Report fire to the fire department. Dial 911. Notify fire department of location of fire, extent of fire/flames/smoke, type or cause of fire, if known.

5. If possible, confine the fire by closing all doors and windows. If there is time, turn off electricity

6. If possible, extinguish fire using fire extinguisher(s).

Procedure

1. If a fire occurs in your area, quickly evacuate all individuals who are in immediate danger. All office exits are to be marked and illuminated. Building exits are also to be marked and illuminated.

2. Keep all corridors clear of any equipment, supplies, or debris.

3. Fire exits should not obstruct or blocked at any time.

4. Close the door to prevent the fire from spreading.

5. If the fire is minor, use the fire extinguisher to put it out.

Minor fires are defined as fires that are localized to a small corner or table, and do not present an immediate danger of spreading. The fire extinguisher can be used to put out fires associated with paper, drapes, computer equipment, wiring, wood, oil, paint, gasoline, and solvents. Do not attempt to extinguish a fire that is moving and/or growing.

6. Once the fire is successfully extinguished, the Office Lead shall contact the Fire Department to notify them of the incident.

7. If the fire is moving or spreading rapidly, the person finding the fire shall be responsible for assigning an individual to notify the staff of the fire and to call the Fire Department

8. All individuals shall evacuate the building through the main entrance into the parking lot in accordance with the evacuation policy. Employees shall assist any non-ambulatory or elderly patients upon evacuation. Do not use the elevators for evacuation. Non-ambulatory or elderly patients should be assisted in the stairwell by employees.

9. Upon evacuation, the front desk staff shall position themselves outside of all entrances into the building to prevent anyone from entering.

10. The Office Lead shall take a formal count of all personnel to determine if all employees have evacuated.

11. Do not re-enter the building under any circumstances.

Prevention Reminders:

- Electrical cords and plugs should be routinely checked for fraying.
- Turn off all electrical equipment before leaving for the day, i.e., the coffeepot.

Attachment 2: Emergency Contact Forms (Resource)

EMERGENCY RESPONDERS & BUSINESSES CONTACT LIST

Date of Last Update:		Updated By:	
	Telephone	**Email**	**Contact Person**
EMS Provider			
Fire Service			
Law Enforcement			
Gas or Propane			
Equipment Provider(s)			
•Air Conditioner			
•Heating			
•			
•			
•			
Facility Management			
Facility Maintenance			
Property Insurance			
Liability Insurance			
Information Technology Support			
Medical Supply & Equipment			
•Vendor			
•			
•			
•			
•			
•			
•			
•			
Local Emergency Management Agency			
Local Red Cross			
Community Partners			
•Partner			
•			
•			
Other Numbers			

STAFF EMERGENCY CONTACT LIST

If a response is activated, each person will call the next two people on the list. Redundant calls are ok. If you cannot reach one of the people you call, leave a message (if possible) and call the next person. Note the name of the person you could not reach and call again one hour later. If unsuccessful, report name to Incident Manager

Date of Last Update:			**Updated By:**		
Name	**Position**	**Preferred Phone #**	**Home Phone**	**Cell Phone**	**Email**
	Executive Director				
	Medical Director				
	Nursing Director				
	Operations/Office Manager				
	HR Director				
	Risk Manager				
	Safety Manager				

Attachment 3: Site Evacuation Plan (Sample)

Policy

All employees shall be familiar with the disaster plans to assist in a safe evacuation of the building.

Procedure

1. An evacuation plan is required to be posted and accessible to patients and employees.

2. In the event of evacuation, all employees, including physicians, are required to assist in the safe evacuation of patients.

3. Exit signs are clearly posted.

4. Employees shall become familiar with the emergency exits and exit plan.

5. Evacuation of ambulatory patients.

- Patients, staff, and any other individuals shall be directed to evacuate away from the danger area.
- Do not use elevators.
- Back office staff shall be responsible for supervising the evacuation of the exam rooms.
- Front office staff shall be responsible for supervising the evacuation of the reception area.
- Individuals should be calmly instructed to collect their belongings and follow you to the nearest exit.

6. The Office Lead shall act as the designated person to instruct all employees during the evacuation and of the steps necessary once the evacuation has been completed. All employees should locate the Office Lead for their office/suite for further instructions. The Office Lead will take count of employees to ensure that everyone has evacuated safely. In buildings where one or more offices are occupied by the company, each Office Lead shall be responsible for their individual suite.

7. When deemed safe, the Office Lead shall instruct employees in pairs to re-enter the building to perform the following tasks:

- Unplug all machinery and lock all cabinets containing medication;
- Turn off gas, water and electricity to the building;
- Survey the damage and look for any individuals who may not have evacuated;
- Retrieve the emergency drug box to provide emergency care for any individuals in need.

8. The Office Lead shall designate a person to call the Practice Management Director or Operations Manager.

9. No front office or back office staff shall leave the parking area unless instructed to do so by the Office Lead, Practice Management Director or Operations Manager.

10. All physicians are required to remain in the parking lot until dismissed by the Practice Management Director or Operations Manager.

Note: To create a custom Evacuation Route Floor Plan, see SFHP FSR Resources

Attachment 4: Employee Alarm System (Sample)

Policy

Employers must install and maintain an operable employee alarm system that has a distinctive signal to warn employees of fire or other emergencies, unless employees can promptly see or smell a fire or other hazard in time to provide adequate warning to them. The employee alarm system must comply with § 1910.165.

Procedure

A. The employer shall assure that all employee alarm systems are maintained in operating condition except when undergoing repairs or maintenance.
B. The employer shall assure that a test of the reliability and adequacy of non-supervised employee alarm systems is made every two months.
C. A different actuation device shall be used in each test of a multi-actuation device system so that no individual device is used for two consecutive tests.
D. The employer shall maintain or replace power supplies as often as is necessary to assure a fully operational condition.
E. Back-up means of alarm, such as employee runners or telephones, shall be provided when systems are out of service.
F. The employer shall assure that manually operated actuation devices for use in conjunction with employee alarms are unobstructed, conspicuous, and readily accessible.

Reference: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.165

Attachment 5: Personnel Training Log (Resource)

EVIDENCE OF STAFF TRAINING
PERSONNEL TRAINING LOG

Employee's Name: _____ Date of Hire: _____

Employee's Position: _____ License Number: _____

Trainer or Learning Management System (LMS): _____

Annual Trainings

Topic	Brief description of training content	Training Dates			
Infection Control & Universal Precautions					
Blood Borne Pathogens Exposure Prevention					
Biohazardous Waste Handling					

Trainings Upon Hire (and as needed)

Topic	Brief description of training content	Training Date
Fire Safety & Prevention		
Non-Medical Emergency Procedures: natural disaster (e.g. earthquakes), workplace violence, etc.		
Medical Emergency Procedures & Action Plan		
Patient Confidentiality		
Informed Consent, including Human Sterilization		
Prior Authorization Requests		
Grievance/Complaint Procedure		
Child, Elder, Domestic Violence Abuse		
Sensitive Services/Minors' Rights		
Health Plan Referral Process/Procedures/Resources		
Cultural & Linguistics		
Disability Rights & Provider Obligations		

Trainings as needed

Topic	Brief description of training content	Training Date
Medication Administration Methods		
Operation of Medical Equipment or Performance of Clinical Laboratory Procedures		

03/17/2022

Note: See SFHP FSR Resources for Staff Training Logs

Attachment 6: Workplace Violence Protocol (Resource)

Workplace Violence Protocol

I. Any staff member involved in an exchange with a patient or other visitor, which he/she perceives to be escalating, will:

A. Ask the visitor to remain calm. If the discussion continues to escalate, he/she will notify the supervisor/practitioner

B. Ensure the safety of staff, patients, and visitors

C. If alone in the office, ask the visitor to leave

D. If the situation continues to escalate, the visitor does not leave, or at any time the staff member feels threatened, Dial 911 to summon police

II. Any staff member involved in an exchange with a patient or other visitor, which he/she perceives to be escalating, will:

A. Immediately dial 911

B. Notify the supervisor/practitioner

Attachment 7: Emergency Earthquake Plan (Resource)

Policy

All employees shall be familiar with the disaster plans to assist in the event of an earthquake, and to inform employees of the proper safety procedures in the event of an earthquake.

Procedure

A. Remain calm at all times. Reassure others to remain calm.
B. Outside meeting place is:

   _____

C. Immediately instruct patients and any other individuals in the room to find protection under something structurally sound (desk, sturdy fixture) or braced in a doorway. If unable to locate a safe place, use items such as cushions, mattresses, or chairs for protection. Remain in that location/position until the earthquake/shaking is over.
D. Staff and patients should not leave the building during the earthquake.
E. Stay away from windows.
F. If the earthquake appears to be minor (no damage noted, and all
G. systems still functioning) continue working.
H. If the earthquake appears to be major (damage noted and systems are not operational) evacuate the building through the main entrance into the parking lot in accordance with the evacuation policy.
I. In the event that a patient or employee is injured and is not trapped, do not attempt to move the individual alone. Call for assistance from another adult.
J. In the event that a patient or employee is injured and is trapped, do not attempt to move the individual if the earthquake is still shaking. Wait for the earthquake to end. Call for assistance from another adult. Any attempts made to free the individual should not increase risk to others.
K. If a trapped individual is unable to be freed, immediately evacuate the building and notify emergency services (911). Stay outside the building until the emergency personnel have arrived to assist in locating the trapped individual.
L. Do not re-enter a damaged building unless instructed to do by emergency personnel.

Note: Earthquakes are usually followed by a series of smaller, yet potentially dangerous aftershocks. Continue to follow the procedures above to prevent possible injury.

Attachment 8: Emergency Terrorist/Bomb Plan (Resource)

Policy

All employees shall become familiar with the disaster plans to assist in the event of a bomb threat. To inform employees of the proper safety procedures in the event of a bomb threat, do the following:

Procedure

1. When a threatening phone call has been received, it should be documented in detail, including the time received and gender of the caller. Be attentive to any distinguishing background noises or characteristics of the caller's voice. Take note of the phone line the call came in on.

2. The Police Department should be notified immediately by the Office Lead.

3. The Office Lead shall inform the staff of the threat and ask each person to search their area for suspicious looking objects. Other areas such as restrooms, utility closets, and stairwells should be searched by an employee designated by the Office Lead.

4. If a suspicious object is discovered, the area should be sealed off and the Office Lead notified.

5. All steps should be taken to continue with regularly scheduled patient care, unless instructed differently by the Office Lead or Law Enforcement.

6 If determined unsafe by the Office Lead (in conjunction with the Police Department) the building shall be evacuated through the main entrance into the parking lot in accordance with the evacuation plan.

Other:

Lockdown

An act of violence in the workplace could occur without warning. If loud "pops" are heard and gunfire is suspected, every employee should know to hide and remain silent. They should seek refuge in a room, close and lock the door, and barricade the door if it can be done quickly. They should be trained to hide under a desk, in the corner of a room and away from the door or windows. Multiple people should be trained to broadcast a lockdown warning from a safe location.

Reference: https://www.ready.gov/business/implementation/emergency

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Exit Sign
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	29 CFR §1910.37: Maintenance, safeguards, and operational features for exit routes.
Agency/Organization Source:	Occupational Safety and Health Administration
Agency/Organization URL	https://www.dir.ca.gov/title8/3216.html

Background:

Site environment is safe for all patients, visitors, and personnel.

Standard:

Exit doors are clearly marked with "Exit" signs. Signs must be posted in visible areas, such as hallways, exam rooms and patient waiting areas.

Each exit sign must have the word "Exit" in plainly legible letters not less than six inches (15.2 cm) high, with the principal strokes of the letters in the word "Exit" not less than three-fourths of an inch (1.9 cm) wide.

While 29 CFR [1910.37(b)] does not specifically require employers to provide exit signs which can be understood by persons with disabilities, in keeping with the policies of the Americans with Disabilities Act, Occupational Safety and Health Administration (OSHA) strongly encourages all employers to provide such signage whenever appropriate.

Purpose:

Exit doorways are unobstructed and clearly marked by a readily visible "Exit" sign.

Information:

Standard 29 CFR 1910 Subpart E says the exit routes have to be located as far away from each other as possible so that if one route is blocked by fire or smoke, employees can use the other route to escape.

However, a single exit route is allowed where the number of employees, the size of the building, or the arrangement of the workplace would enable all employees to exit safely during an emergency.

Fire escapes, accessible windows, or other means of escape should be available where only one exit route is provided.

In some workplaces, more than two exit routes may be necessary to safely evacuate all employees.

Appendix A: Printable Exit Sign

Appendix B: Exit signs are available for purchase online. See examples below.

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SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Diagram Evacuation Routes
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	8 CCR, 1910 Subpart E App, Exit Routes and Emergency Planning, Exit Routes, Emergency Action Plans, and Fire Prevention Plans. Subpart E: 1910.38 Employee emergency plans
Agency/Organization Source:	United States Department of Labor, Occupational Safety and Health Administration (OSHA) https://www.govinfo.gov/content/pkg/CFR-2013-title29-vol5/pdf/CFR-2013-title29-vol5-sec1910-38.pdf
Agency/Organization URL	https://www.osha.gov/SLTC/etools/evacuation/floorplan_demo.html

Background:

Site environment is safe for all patients, visitors, and personnel.

Procedure:

Evacuation Routes: Clearly marked, easy-to-follow escape routes are posted in visible areas, such as hallways, exam rooms and patient waiting areas. The minimum clear passage needed for a single wheelchair is 36 inches along an accessible route but may be reduced to a minimum of 32 inches at a doorway.

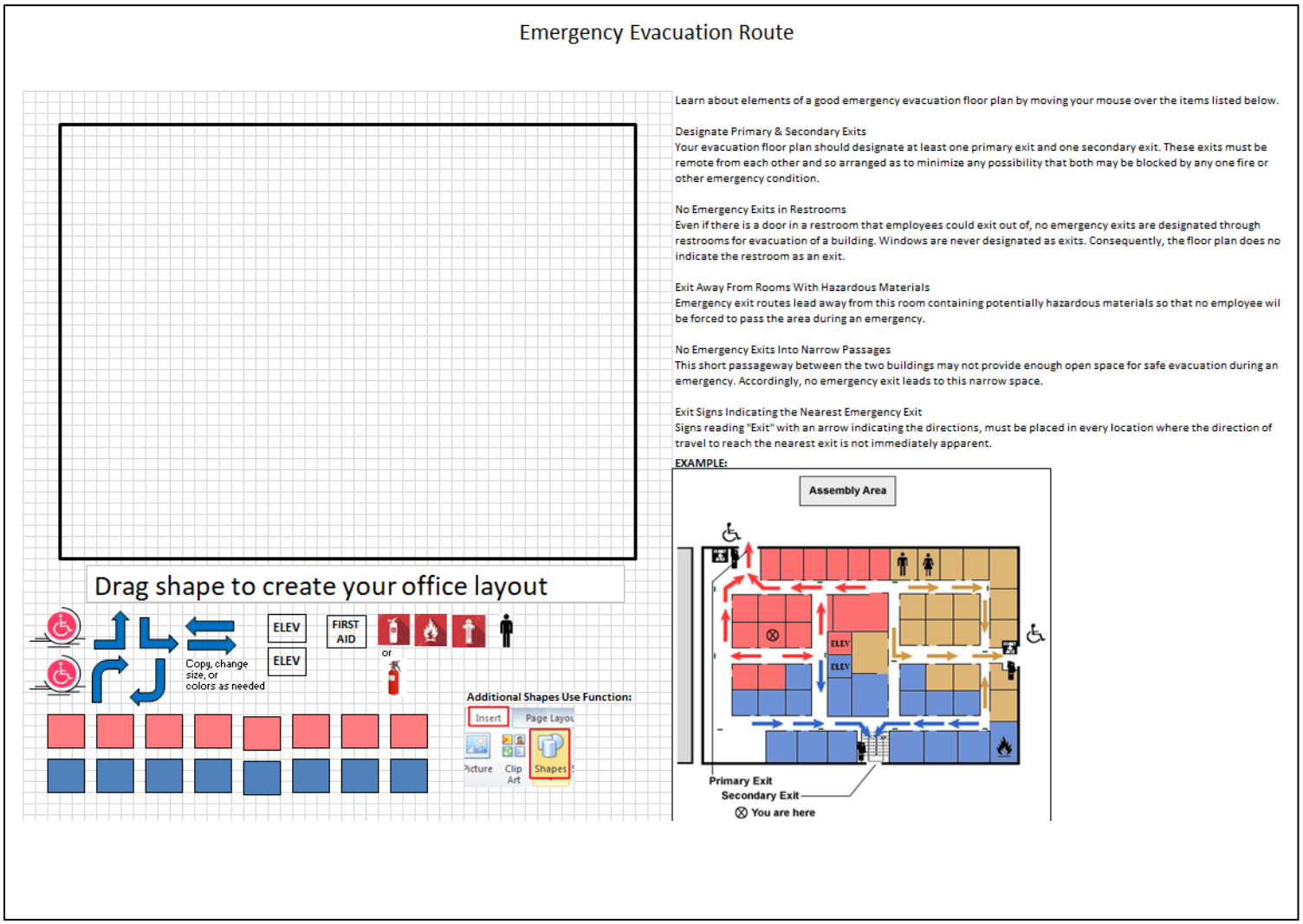
Purpose:

The use of floor plans or workplace maps which clearly show the emergency escape routes should be included in the emergency action plan. Color coding will aid employees in determining their route assignments.

Appendix A:

Emergency Evacuation Diagram Guide (Example 1)

Excel Tool to Create Your Own Floor Plan Evacuation Route (See Excel Template)



Appendix B:

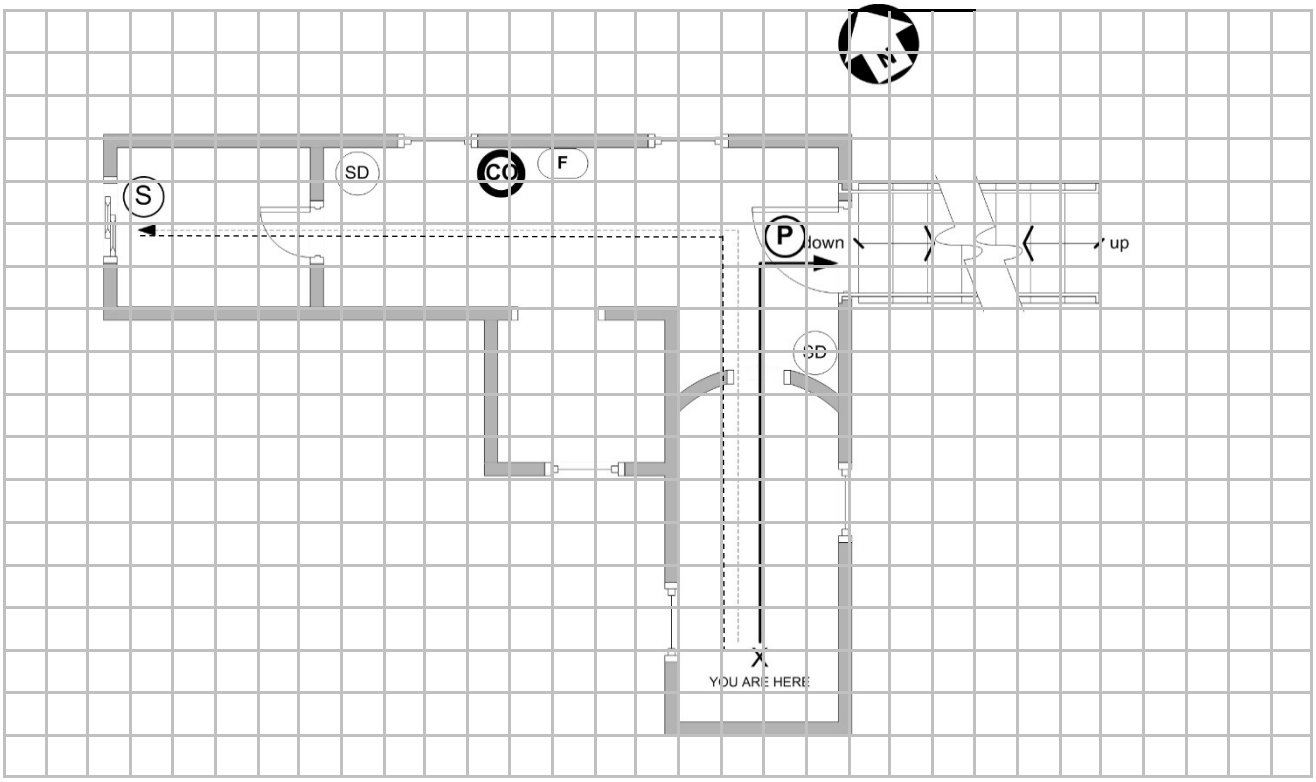
Emergency Evacuation Diagram Guide (Example 2)

Inside Floor Plan Guidelines

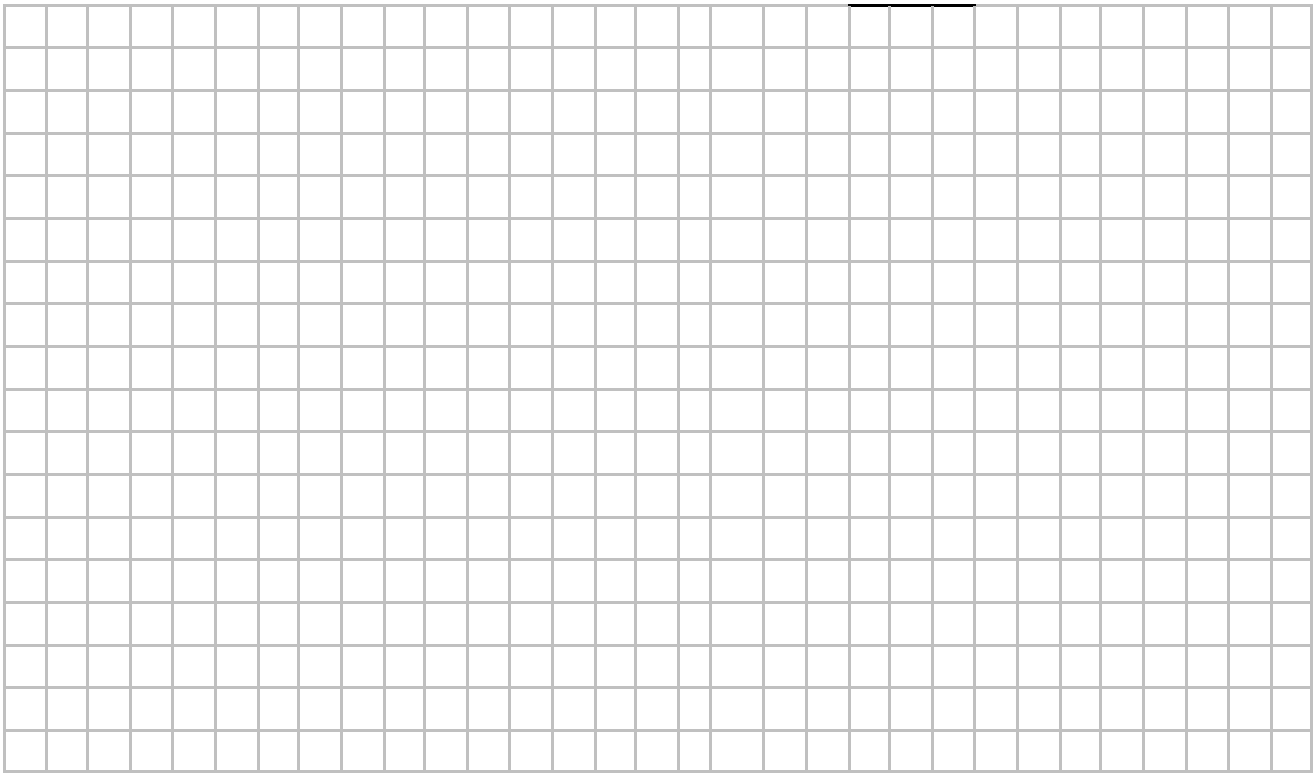
1. Duplicate the following page for the clinic.
2. Draw an outline of the clinic as if you are looking down through the ceiling.
3. Show the location of doors, walls, and windows so that each room or space is bordered with a line.
4. Label items on the diagram using the symbols in the Items Checklist on this page.
5. Label the designated primary and secondary evacuation routes.
6. It is required that a copy of the evacuation diagram be posted in a visible location.
7. A diagram is posted in each room and includes the escape path from that room to the nearest exit.

	Items Checklist	
	Item	**Symbol**
☐	Carbon Monoxide Detector	(CO)
☐	Smoke Detector	(SD)
☐	Exit	(EXIT)
☐	Fire Extinguishers	(F)
☐	Primary Evacuation Route	P
☐	Secondary Evacuation Route	S
☐	Fire Escapes	(FE)
☐	Stairs	
☐	You Are Here	**X**

Sample Drawing



Template



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SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Fire Fighting/Protection Equipment/Inspection
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	Medicaid provider compliance with National Fire Protection Association (NFPA) 101 Life Safety Code (LSC) and NFPA 99 Health Care Facilities Code (HCFC) 29 CFR 1910.157
Agency/Organization Source:	San Francisco Fire Department
Agency/Organization URL	https://sf-fire.org/services/inspections

Background:

A fire safety inspection of each primary care provider office is required to ensure that reasonable fire safety exists for that business. The Inspection Section of the Bureau of Fire Prevention inspects the life safety components of new building construction, building remodels, and fire sprinkler & fire alarm systems to ensure compliance with the San Francisco Fire Code. The City is geographically divided into 17 Fire Inspection districts (see Fire Inspection District Map at https://sf-fire.org/inspections). A Fire Inspector is assigned to each of these Fire Inspection Districts and responsible for conducting inspections within his/her area.

San Francisco Fire Department (SFFD) Binder:

The San Francisco Fire Department requires testing of all emergency equipment. **Records of all tests and inspections shall be maintained in a binder marked "SFFD" and stored on the premises for the fire department's review.** Depending on your building's features, some, or all the items listed below require your attention:

1) Facility Emergency Plan (Update plan as needed)
2) Fire Safety Director Certificate (Valid for 5 years)
3) Fire Alarm UL Certificate (Expiration date on certificate)
4) Annual Fire Drill log **(Must include date of last fire inspection and results)**
5) Annual Fire Alarm Test Certificate, includes the testing of (but not limited to):
    a) Pull Stations
    b) Visual Warning Devices
    c) Audibility of Fire Alarm System

d) Waterflow and Tamper Devices

e) Smoke Detectors

f) Firefighters' Phone System

g) Stairwell Emergency Phones

h) Heat Sensors.

6) Sprinkler/Standpipe (5-yr Certification and Annual inspection)

7) Fire Pump Test (Diesel and Electric pumps)- (Annual and Weekly)

8) Emergency Generator- (Weekly and Monthly)

9) Elevator Emergency Equipment and Key Operation (Quarterly)

10) Exit and Emergency Lighting (Quarterly)

11) Emergency Exit and Release Devices (Annually)

12) Smoke Control Systems and Fire/Smoke Dampers (Quarterly)

13) Roll-up type fire doors (Annual)

14) Firefighter Air Replenishment System (Semi-Annual)

15) Special Extinguishing Systems – including, but not limited UL300 or Halon systems (Semi-Annual)

Accessed from: https://sf-fire.org/services/inspections

Appendix A:

San Francisco Fire Department

Division of Fire Prevention
& Investigation

September 8, 2019

INFORMATIONAL BULLETIN

Effective September 8, 2019, San Francisco Ordinance 0192-19 requires a fee of $130.00 per hour to cover the costs of an inspection to grant a fire clearance. Payment for the referral inspection must be paid in advance prior to scheduling a Fire Department inspection. Additional inspections may require an additional fee at a rate of $130.00 per hour. Payment may be made in person, by mail, or credit card by phone. Complete the lower portion of this form, detach, and enclose it with your payment. Please make check payable to:

San Francisco Fire Department
Bureau of Fire Prevention - Referral
698 Second Street, Room 109
San Francisco, CA 94107

When ready for an inspection and the inspection fee has been paid, please call the Bureau of Fire Prevention at (415) 558-3300 and request to speak with the District Inspector assigned to your property address to schedule an inspection.

Unless properly notified, the SFFD will deny or cancel any referral that is more than 90 days old from date of Referral Form. Thank you.

Request for PD, DPH or Entertainment Commission Referral Inspection

Enclose a check for $130.00 made payable to the San Francisco Fire Department.

APPLICANT NAME: _____

PHONE NUMBER: _____

ADDRESS OF BUSINESS: _____

NAME OF BUSINESS: _____

TYPE OF BUSINESS: _____

MAILING ADDRESS: _____

Telephone: (415) 558-3300
Fax No: (415) 558-3323

698 Second Street, Room 109
San Francisco, CA 94107

Revised: 9/8/19

Note: See San Francisco Fire Department site for Informational Bulletin

Appendix B:

San Francisco Fire Department

Division of Fire Prevention
& Investigation

SFFD REFERRAL INSPECTION GUIDELINE/CHECKLIST

A fire safety inspection of your business is required to ensure that reasonable fire safety exists for the business. To facilitate the approval of your application in a timely manner and to minimize additional inspection fees, make sure your business complies with the following requirements prior to scheduling an inspection:

- ❑ 1. Property address posted and visible from the street (minimum requirement 4-inch numbers on contrasting background).
- ❑ 2. Exit doors to open from the inside without the use of a key, special knowledge, or effort.
  EXCEPTION: Key-locking hardware may be used on the inside of the main door to your business if a readily visible and durable sign is installed on, or adjacent to, the door stating, "THIS DOOR MUST REMAIN UNLOCKED WHEN THE BUILDING IS OCCUPIED."
- ❑ 3. Exits, and access to exits, maintained clear of obstructions.
- ❑ 4. All illuminated exit signs operational. Replace burned out bulbs.
- ❑ 5. Maximum occupant load posted for public assembly occupancies (>49 occ.).
- ❑ 6. Fire extinguishers installed, maintained, and serviced annually.
- ❑ 7. Fire extinguishers have a current State Fire Marshal (SFM) service tag attached.
- ❑ 8. Cooking area has one Type K fire extinguisher with current SFM service tag attached.
- ❑ 9. Automatic fire suppression system (hood & duct system) serviced semi-annually if installed. A current SFM service tag shall be attached to the system for proof of service.
- ❑ 10. Hoods, filters, and exhaust flues shall be clean.
- ❑ 11. No storage in boiler rooms, mechanical room, and electrical equipment room.
- ❑ 12. Existing ground floor pipe casing holes shall not be covered.
- ❑ 13. Extension cords shall not be used as a substitute for permanent wiring.
- ❑ 14. Where they exist, proof of sprinkler and standpipe systems five year maintenance service.
- ❑ 15. Where a fire alarm exists, proof of testing and maintenance in accordance with the San Francisco Fire Code.
- ❑ 16. Operator name and phone number posted at unattended parking lots.
- ❑ 17. Vehicle barrier(s) to protect public way and adjacent buildings maintained in parking lots.
- ❑ 18. Entire parking lot illuminated to (1) foot-candle (minimum) at the pavement.
- ❑ 19. Minimum 30-inch aisle for access to entire area of parking lot or garage maintained.
- ❑ 20. Parking garage ventilation systems maintained.
- ❑ 21. Vehicle exit and entrance width (minimum 15 feet) maintained.

NOTED: All of the above requirements may not apply to your facility or business. For an example, if a sprinkler system is not installed in facility or business that requirement is not applicable to your facility or business.

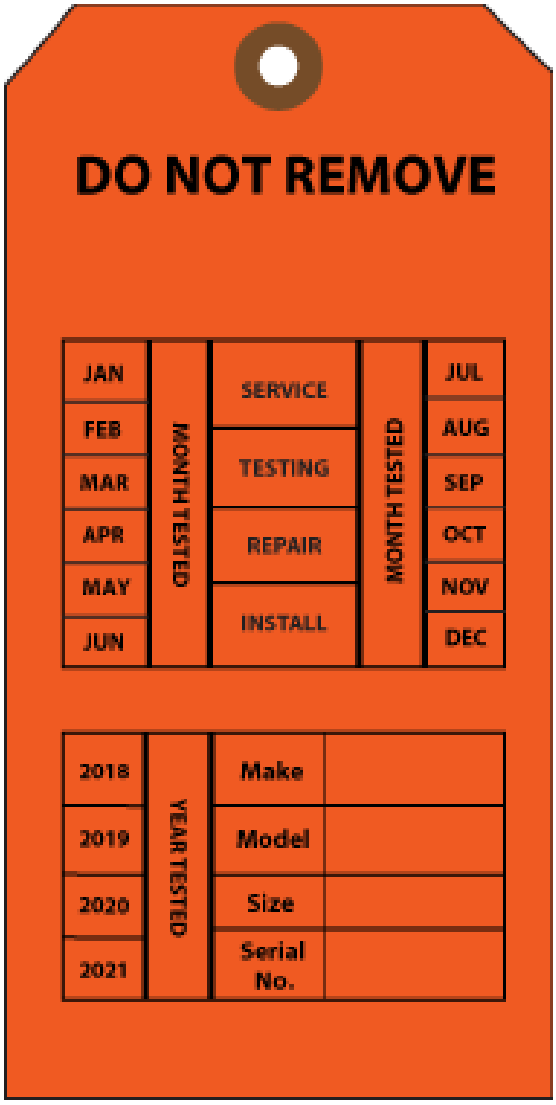
If you have questions regarding the above items, please contact the Bureau of Fire Prevention at (415) 558-3300 and ask for the District Inspector assigned to your business.

Telephone: (415) 558-3300
Fax No: (415) 558-3323

698 Second Street, Room 109
San Francisco, CA 94107

Revised: 9/1/17

Note: See SFFD REFERRAL INSPECTION GUIDELINE/CHECKLIST



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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Employee Alarm System		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 29 CFR 1910.37		

Purpose:

OSHA's employee alarm systems standard applies to all employers that use an alarm system to satisfy any OSHA standard that requires employers to provide an early warning for emergency action, or reaction time for employees to safely escape the work place, the immediate work area, or both. [29 CFR 1910.165]

Definition:

The employee alarm shall be capable of being perceived above ambient noise or light levels by all employees in the affected portions of the workplace. Tactile devices may be used to alert those employees who would not otherwise be able to recognize the audible or visual alarm. [29 CFR 1910.165(b)(2)]. The two most common types of alarms are audible and visual devices.

Policy Statement:

Employers must install and maintain an operable employee alarm system that has a distinctive signal to warn employees of fire or other emergencies, unless employees can promptly see or smell a fire or other hazard in time to provide adequate warning to them. [29 CFR 1910. 37] OSHA: For those employers with 10 or fewer employees in a particular workplace, direct voice communication is an acceptable procedure for sounding the alarm provided all employees can hear the alarm. Such workplaces do not need a back-up system.

Alert and Alarm Systems

If you own or manage your own building, it is up to you to install emergency alert systems. Many commercial alarm companies provide all-in-one solutions that include security alarms, fire alarms and even carbon monoxide detectors.

Weather alert radios pick up signals from National Weather Service radio stations to alert the public of both weather and non-weather related watches and emergencies. Like smoke detectors, these radios can be programmed to sound an alarm so that you and your staff know if there is a danger or threat of danger in your area.

Designate Assembly Areas

Designate an assembly area where everybody in the office will rendezvous for a headcount and further instructions. Ideally, your assembly area should be easily accessible but also safe. For example, you might opt to meet at a restaurant or grocery store across the street from your building.

Tip

Many people over-rely on technology such as cell phones and computers to provide information during a disaster. Unfortunately, cell towers and the power grid may be damaged or disrupted during emergencies. Battery powered and hand crank radios can provide you and your staff with accurate, up-to-date information even when you can't get cell reception and the electricity doesn't work.

Educate Your Employees

- Information about emergency processes should be included in your onboarding process. In addition, take time during all-hands meetings to go over safety information with your team.
- Employees who have responsibilities in disaster situations should be provided with education and training. This may include training with first responders, Community Emergency Response Teams, or the Red Cross.
- Don't assume that one class or notification is enough training for your staff. Provide refresher courses and training throughout the year.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Medical Emergency Response Protocol		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	8 CCR §3220; 22 CCR §51056, §53216, §75031; 28 CCR §1300.67, §1300.80; American Academy of Family Practice (AAFP) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Personnel are trained in procedures/action plan to be carried out in case of medical emergency on site.

DHCS Standard:

- Staff can describe site-specific actions or procedures for handling medical emergencies until the individual is stable or under care of local emergency medical services (EMS).
- There is a written procedure for providing immediate emergent medical care on site until the local EMS is on the scene. Although site proximity to emergency care facilities may be considered when evaluating medical emergency procedures, the key factor is the ability to provide immediate care to patients on site until the patient is stable or EMS has taken over care/treatment.
- When the physician or non-physician medical practitioner (NPMP) is not on site, staff/MA may call 911, and CPR-certified staff may initiate CPR if needed.
- Non-CPR-certified staff may only call 911 and stay with the patient until help arrives.

Policy:

To ensure that a patient's needs are met in an emergency situation. Appropriate evaluation and management of patients in emergency situations are dealt with so as to optimize the patient's health and well-being. The medical office personnel will be trained in patient emergency procedures. It is recommended that the practitioner and at least one nurse maintain CPR certification. If emergency equipment is kept, it is also required that the equipment be kept current and complete and assessed/ documented for same on a regular basis.

Procedure:

1) When a potential medical emergency is recognized, the physician or nurse is notified by calling for help. Two persons will stay with the patient, if possible.
2) 911 will be called if patient care needs are beyond the scope of the practitioner's office.
3) If possible, a 3-4 member team will be formed with one person (usually the practitioner or RN) in charge giving directions.
4) All other staff will continue patient services as usual and maintain a calm attitude.
5) The practitioner or nurse in charge will conduct a physical assessment of the patient and carry out essential medical procedures with the assistance of other designated staff.
6) A medical assistant will move available emergency equipment and supplies to the patient care area.
7) Urgent patient conditions, such as elevated fever or pain should be routed to the physician or nurse. If a clinician speaks to the patient, the clinician should review the patient's record, and through discussion with the patient, assess the patient's condition to determine:
8) Need to see the physician and timeframe for the visit.
9) Need for medication or adjustment to current medication.
10) Immediate recommendations for patient's next steps.
11) Severity of the patient's condition.
12) Behavior modification, such as limitations on physical activity, etc.
13) Time interval for follow-up and next communication.

First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Emergency Phone Number Contacts
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	
Agency/Organization Source:	
Agency/Organization URL	

Background:

Emergency health care services are available and accessible 24 hours a day, 7 days a week.

Purpose:

Staff is able to describe site-specific action or procedures for handling medical emergencies until the individual is stable or under care of local emergency medical services (EMS). There is a written procedure for providing immediate emergent medical care on site until the local EMS is on the scene. Although site proximity to emergency care facilities may be considered when evaluating medical emergency procedures, the key factor is the ability to provide immediate care to patients on site until the patient is stable or MES has taken over care/treatment. 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 still only call 911 and stay with the patient until help arrives.

Emergency Phone Number list:

Posted in an accessible and prominent location(s) and includes:

- Local emergency response services (e.g., fire, police/sheriff, ambulance).
- Emergency contacts (e.g., responsible managers, supervisors).
- Appropriate State, County, City, and local agencies (e.g., local poison control number).

The list should be dated, and telephone numbers updated annually and as changes occur.

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Appendix A (See next page)

EMERGENCY CONTACT SHEET

OFFICE NAME _____

OFFICE ADDRESS_____

FOR EMERGENCY SERVICES: DIAL 911

POISON CONTROL 1-800-222-1222	POLICE _____	FIRE _____	AMBULANCE _____	HOSPITAL _____

Emergency Numbers

HOSPITAL: _____

MD # _____

MD # _____

OFFICE MANAGER: _____

GAS LEAK/EMERGENCY: _____

POWER OUTAGE#: _____

CLOSEST URGENT CARE: _____

FACILITIES: _____

Locations

FIRE EXTINGUISHERS: _____

FIRST AID BOX: _____

GAS ON/OFF VALVE: _____

WATER ON/OFF VALVE: _____

BREAKER PANEL: _____

Family Violence Resources in San Francisco

June 2019

Area code 415 for all numbers unless otherwise noted

*24hr/7days/week

Police Department/District Attorney	
Emergency Police and Fire	911
Non-emergency Police (SFPD)	553-0123
District Attorney (DA)	553-1751
DA's Victim Services	553-9044
Reporting Lines for Abuse	
Adult/Elder Protective Services	355-6700/1-800-814-0009
Domestic Violence Reporting (SVU/SFPD)	553-9225
SF DHS Child Abuse Reporting	558-2650/1-800-856-5553
Crisis Intervention	
Domestic Violence	
*Asian Women's Shelter	1-877-751-0880
*La Casa de Las Madres (Hotline/Text line)	1-877-503-1850/200-3575
*National Domestic Violence Hotline	1-800-799-7233
Online chat: www.thehotline.org	
*Riley Center	255-0165
*WOMAN, Inc. (English/Spanish)	864-4722/1-877-384-3578
Sexual Assault/Sexual Violence	
Mujeres Unidas y Activas (Spanish only)	431-2526
*National Sexual Assault Hotline	1-800-656-HOPE (4673)
Online chat: www.rainn.org	
*San Francisco Women Against Rape (SFWAR)	647-RAPE (7273)
Child/Youth Crisis	
*CA Youth Crisis Line (Phone support for youth ages 12-24 and adults supporting youth)	1-800-843-5200
Online chat: www.calyouth.org	
*Comprehensive Child Crisis Services	970-3800
*Huckleberry Youth Programs	621-2929
*Larkin Street Youth Services	800-447-8223/800-669-6196
Child/Youth Trauma and Sexual Abuse	
Child and Adolescent Support, Advocacy, and Resource Center (CASARC)	206-8386
*Childhelp National Child Abuse Hotline	1-800-422-4453
*Huckleberry Youth Programs	621-2929
*La Casa de Las Madres (Teen line)	1-877-923-0700
Mental Health/Substance Abuse Crisis	
*Behavioral Health Access Center	255-3737
Comprehensive Crisis Services	970-3800
*National Helpline	1-800-662-HELP (4357)
*SF Suicide Prevention	781-0500/1-800-273-8255
Online chat: www.sfsuicide.org	
Westside Crisis Clinic	355-0311 x1220
245 11th St (Drop-in center hours: Mon-Fri 8am-6:00pm, Sat 9am-4pm, arrive 30 min before doors open to be seen that day)	
*ZSFG Psychiatric Emergency	206-8125
Elder Crisis	
*Friendship Line for the Elderly	1-800-971-0016

Crisis Shelters	
Domestic Violence Shelters - 3 Confidential Locations	
*Asian Women's Shelter	1-877-751-0880
*La Casa de Las Madres	1-877-503-1850
*Riley Center	255-0165
Youth Crisis Shelters	
*Huckleberry House (Shelter age 11-17)	621-2929
Larkin Street Youth Services	
*Diamond Youth Shelter (Shelter under age 17)	1-800-669-6196
*Lark-Inn for Youth (Shelter ages 18-24)	1-800-447-8223
Counseling: Resources/Referrals	
Counseling: Survivors of Domestic Violence	
Cameron House (Services for Asian communities)	781-0401
Community United Against Violence (CUAV) (Services for LGBTQ communities)	333-HELP (4357)
427 South Van Ness Avenue (Between 15th and 16th Streets) (Drop-in center and phone line hours: Wed 4-8pm)	
Glide Women's Center	674-6026
Homeless Prenatal Program	546-6756
Jewish Family & Children's Services	449-1200
*La Casa de Las Madres	1-877-503-1850
1269 Howard St (Drop-in center hours: Mon-Fri 8:30am-3:30pm)	
Mujeres Unidas y Activas (Spanish only)	431-2526
Riley Center	977-1270
1175 Howard St., "Wellness Center" building (Drop-in center hours: Mon & Thurs 9am-12pm & 1:30-4pm)	
Safe and Sound Family Support Center (Counseling and referrals for survivors/families with children age 0-6)	441-KIDS (5437)
Shalom Bayit	1-866-SHALOM-7 (1-866-742-5667)
Trauma Recovery Center	437-3000
*WOMAN, Inc.	864-4722
26 Boardman Place (Drop-in center hours: Wed (11am-12:30pm), Friday (2-3:30pm)	
Counseling: Survivors of Sexual Assault	
SF Women Against Rape (SFWAR) (Peer and group counseling)	861-2024
ZSFG Trauma Recovery/Rape Treatment Center	437-3000
Counseling: Children, Youth, and Family	
APA Family Services	617-0061
Cameron House (Services for Asian communities)	781-0401
Child Trauma Research Program (Intake line)	206-5311
Family Service Agency	474-7310
Homeless Prenatal Program	546-6756
*Huckleberry Youth Programs (Therapy age 11-21)	621-2929
Instituto Familiar de La Raza	229-0500
La Casa de Las Madres	503-0500
Larkin Street Youth Services	673-0911
Parents Place (Jewish Family & Children's Services)	359-2443
*TALKLine (Parenting support line)	441-KIDS (5437)

Counseling: Elder Services	
*Friendship Line for the Elderly	1-800-971-0016
Institute on Aging (Elder counseling referral)	750-4111
Counseling: Mental Health & Substance Use	
*Behavioral Health Access Center	255-3737
1380 Howard St (Drop in hours: Mon-Fri 8am-4:30pm)	
Counseling: Violence Perpetration	
John Hamel & Associates	472-3275
Men in Progress	674-6195
POCOVI (Spanish only)	552-1361
Resolve to Stop the Violence (RSVP)	510-268-8116
Legal Resources	
Asian Pacific Islander Legal Outreach (APILO)	567-6255
Bay Area Legal Aid (BayLegal)	354-6360/800-551-5554
Cooperative restraining Order Clinic	255-0165
Legal Aid at Work (Project Survive)	1-888-864-8335
Legal Assistance for the Elderly	538-3333
SF Bar Association (Mediation services)	782-8905
SF Bar Association (Referral line)	989-1616
Public Health Nursing (PHN)	
Home visits to high-risk prenatal/postpartum women and chronically ill children	1-800-300-9950
Bay Area Domestic Violence Resources	
Alameda County	1-510-536-7233/510-537-2552
Contra Costa County	1-888-215-5555
Marin County	924-6616/924-3456
San Mateo County	1-800-300-1080
Santa Clara County	1-408-279-2962
Solano County	1-866-487-7233
Additional Resources	
HELPLINK	211/1-800-273-6222
LEAP (Look to End Abuse Permanently)	www.leapsf.org
SF City Employee Domestic Violence Liason Program	https://sfgov.org/dosw/city-employee-domestic-violence-liaison-program
SFDPH Women & Children's Health referrals	1-800-300-9950

Electronic version: www.sfdph.org/mcah or www.leapsf.org

Changes? Email ariseproject@ucsf.edu

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Maintenance of all Medical and Laboratory Equipment		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Medical and lab equipment used for patient care is properly maintained.

Definition:

Monitor: The term includes, but not limited to, glucometers, EKG, BP monitors, hemocues, and audiometers.

Policy:

A. All equipment used to measure or assess patient health status/condition is clean.
B. All equipment used to measure or assess patient health status/condition is functioning properly.
C. There is documented evidence that standard operating procedures have been followed for routine inspection/maintenance, calibration, repair of failure or malfunction, and testing and cleaning of all specialized equipment
D. Appropriate written records include calibration or other written logs, work orders, service receipts, dated inspection sticker, etc.
E. All equipment used to measure or assess patient health status/condition is functioning properly. All specialized equipment (e.g., ultrasonography equipment, electrocardiogram (EKG) machine, defibrillator, audiometer, hemoglobin meter, glucometer, scales, etc.) are adequately maintained according to the specified manufacturer's guidelines for the equipment or is serviced annually by a qualified technician.
F. Blood pressure cuffs, monitors, and other related equipment need not be calibrated unless required by the manufacturer. Manufacturer guidelines must be available on site, indicating that it is not necessary to calibrate the equipment.

Procedure:

I. Maintenance of Medical Equipment

A. Operating manuals for medical and lab equipment will 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; and annual cycle for safety/calibration will be adopted

D. Documented proof of servicing will be maintained on site a 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.

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 will be trained on appropriate use and maintenance.

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

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). (Pg. 5)
- There is a written procedure for providing immediate emergent medical care on site until the local EMS is on the scene (See Ex. Pg. 6).
- 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. (See Ex. Pg. 4).
- Documented evidence that emergency medication and equipment is checked at least monthly may include a log, checklist or other appropriate method(s). (See Ex. Pg. 2)

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 (See Ex. Pg. 4). 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: (See Page 2 and 3)

EMERGENCY MEDICATION/ANAPHYLACTICE REACTION MANAGEMENT:

There is a current medication administration reference (e.g. medication dosage chart) available for readily identifying the correct medication dosages (e.g. adult, pediatric, infant, etc.). Package inserts are not acceptable as dosage charts. All emergency medications in the emergency kit/ crash cart must have dosage charts.

Anaphylaxis Kit*	Stock	Lot #	Exp. Date	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
A written emergency protocol for anaphylaxis treatment should be posted in a prominent place and rehearsed regularly. It should include drug dosages for adults, as well as telephone numbers and contact details for resuscitation team, emergency medical services, emergency department, etc.															
Epinephrine (Anaphylaxis) Anaphylaxis 1mg/mL															
(1) X 1 mL vial of injectable diphenhydramine (Benadryl) 50 mg/mL															
(2) X 1 tab of oral diphenhydramine (Benadryl) 25 mg (Oral)															
(3) X 1 mL syringes with safety engineered needles (ESIP). Suggest: Needle gauge: 25G, needle lengths: 3 x 1″; 3 x 5/8″; 3 x 1.5″															
Oxygen Delivery System – tank at least ¾ full Oxygen delivered 6-8 L/minute															
Oral Airways (various sizes)															
Nasal Cannula or Mask															
Ambu bag															
1 Pocket mask															
5 Alcohol swabs															
Other Emergency Medications	**Stock**	**Lot #**	**Exp. Date**	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
Asthma exacerbation, chest pain, hypoglycemia management per American Academy of Family Practice (AAFP) recommendations.															
Naloxone (Narcan®)															
Chewable aspirin															
Nitroglycerin spray/tablet															
Nebulizer or metered dose inhaler															
Glucose															

EXAMPLE - DOSAGE CHART

2019 Site Review DHCS Guidelines
Emergency Medication\Anaphylactic Reaction Management
Medication Administration Reference (e.g. Medication Dosage Chart)

Anaphylaxis Kit*	Adult	Pediatric	Infant
Epinephrine (Anaphylaxis) Anaphylaxis 1:1000 (injectable)	0.01mg/kg IM (up to maximum of 0.5mg)	0.01 mg/kg IM (up to maximum of 0.3mg)	0.01 mg/kg IM (up to maximum or 0.3mg)
(1) X 1 mL vial of injectable diphenhydramine (**Benadryl**) 50 mg/mL	10mg to 50mg IV/IM (NTE 400mg/day) *If IV route, IV push at a rate of ≤25mg/min	1 to 2 mg/kg/dose IV/IM (NTE 50mg/dose) *If IV route, IV push at a rate of ≤25mg/min	1 to 2 mg/kg/dose IV/IM (NTE 50mg/dose)
(2) X 1 tab of oral diphenhydramine (**Benadryl**) 25 mg (Oral)	Take 25mg to 50mg by mouth	Not preferred. Refer to parenteral route or oral solution	Not preferred. Refer to parenteral route or oral solution
Oxygen Delivery System – tank at least ¾ full	Can consider any oxygen delivery systems if appropriate	Nasal prongs or nasal catheters preferred; can consider face mask, bead box, or incubator for older children	Nasal prongs or nasal catheters preferred
Oxygen delivered 6-8 L/minute	6 to 8 L/minute	1 to 4 L/minute	1 to 2 L/minute
Other Emergency Medications	**Adult**	**Pediatric**	**Infant**
Naloxone (Narcan®)	**Nasal (Narcan)**: Spray 4mg (content of 1 nasal spray) in one nostril as a single dose; may repeat every 2-3 minutes in alternating nostrils **Auto-injector (Evzio)**: Inject 2mg (content of 1 auto-injector) IM as a single dose; may repeat every 2-3 minutes with another Evzio auto-injector **Solution injection**: Inject 0.4mg to 2mg IM as a single dose; may repeat every 2-3 minutes up to 10 mg	**Nasal (Narcan):** 4mg (content of 1 nasal spray) as a single does in one nostril; may repeat every 2-3 minutes in alternating nostrils **Auto-injector (Evzio)**: Inject 2mg (content of 1 auto-injector) IM as a single dose; may repeat every 2-3 minutes with another Evzio auto-injector **Solution injection** (age ≥5 years old or ≥20kg): 2mg/kg IM/SQ; may repeat every 2-3 minutes prn	**Nasal (Narcan)**: 4mg (content of 1 nasal spray) as a single does in one nostril; may repeat every 2-3 minutes in alternating nostrils **Auto-injector (Evzio):** Inject 2mg (content of 1 auto-injector) IM as a single dose; may repeat every 2-3 minutes with another Evzio auto-injector **Solution injection** (age <5 years old or ≤20kg): 0.1mg/kg IM/SQ; may repeat every 2-3 minutes prn
Chewable aspirin	Chew 160mg to 325mg nonenteric coated aspirin upon presentation or within 48 hours of stroke	Aspirin is not recommended for patients <18 years of age who are recovering from chickenpox or flu symptoms due to association with Reye syndrome	Aspirin is not recommended for patients <18 years of age who are recovering from chickenpox or flu symptoms due to association with Reye's syndrome
Nitroglycerin spray/tablet	**Tablet:** 0.3mg to 0.4mg sublingually every 5 minutes up to 3 doses **Spray:** Spray 0.4mg (1 spray) sublingually every 5 minutes up to 3 doses	Safety and effectiveness of oral nitroglycerin in pediatric patients have not been established	Safety and effectiveness of oral nitroglycerin in pediatric patients have not been established
Nebulizer or metered dose inhaler (albuterol)	**Nebulizer:** 2.5mg to 5mg every 20 minutes for 3 doses, then 2.5mg to 10mg every 1 to 4 hours prn **MDI** (90mcg/actuation): 4 to 8 inhalations every 20 minutes for up to 4 hours, then 1 to 4 hours prn	**Nebulizer:** 2.5mg to 5mg every 20 minutes for 3 doses, then 2.5mg to 10mg every 1 to 4 hours prn **MDI** (90mcg/actuation)**:** 2 to 10 inhalations every 20 minutes for 2 to 3 doses; if rapid response, can change to every 3 to 4 hours prn	**Nebulizer:** 2.5mg every 20 minutes for the 1st hour prn; if there is rapid response, can change to every 3 to 4 hours prn **MDI** (90mcg/actuation)**:** 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
Glucose	15gm (3-4 tablets) by mouth	10gm to 20gm (0.3gm/kg) by mouth	Not preferred. Parenteral route recommended (IV dextrose or IM glucagon)

7.30.19 Jenny Nguyen, PharmD, SFHP Pharmacy

DHCS Medical Emergency Response Guidelines for PCP Clinic

Emergency Contact List [Emergency contact list prominently placed or demonstrated online as easily accessible.]

YOUR CLINIC INFORMATION

Name of Office:	
Street Address:	
City, Postal Code:	
Telephone Number:	
Fax Number:	
Email:	

OFFICE/NURSE MANAGER

Name:	Primary Contact #:	Alternate Contact #:

EMERGENCY NUMBERS

Fire Department	Police Department	Ambulance Service
Hospital	Poison Control	Alarm Company

Site Access/Safety Emergency phone number contacts are posted.
Local emergency response services, emergency contacts (e.g., responsible managers, supervisors), poison control; dated/updated annually.

DHCS Medical Emergency Response Guidelines for PCP Clinic

CLINIC _____ **YEAR** _____

	Anaphylaxis Management			Asthma Exacerbation			Chest Pain			Hypoglycemia Management			Opioid Overdose Management		
	Annual Verification	Staff Mock Training		Annual Verification	Staff Mock Training		Annual Verification	Staff Mock Training		Annual Verification	Staff Mock Training		Annual Verification	Staff Mock Training	
Written protocol for treatment		Jan			Jan			Jan			Jan			Jan	
Protocol prominently placed		Feb			Feb			Feb			Feb			Feb	
Adult drug dosage chart		Mar			Mar			Mar			Mar			Mar	
Pediatric drug dosage chart		Apr			Apr			Apr			Apr			Apr	
		May			May			May			May			May	
		Jun			Jun			Jun			Jun			Jun	
		Jul			Jul			Jul			Jul			Jul	
		Aug			Aug			Aug			Aug			Aug	
		Sep			Sep			Sep			Sep			Sep	
		Oct			Oct			Oct			Oct			Oct	
		Nov			Nov			Nov			Nov			Nov	
		Dec			Dec			Dec			Dec			Dec	

Instructions: Each year and as indicated, date and initial that the criteria are current and in practice. According to best practices, date and initial the regular occurrences of mock training with staff.

EXAMPLE: **Procedure for Providing Immediate Emergent Medical Care On Site Until the Local EMS is On the Scene.**

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

References: Tip – Use Google Scholar to access articles

Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review

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SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Oxygen Tank Monitoring and Maintenance
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	
Agency/Organization Source:	Food and Drug Administration (FDA)
Agency/Organization URL	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/review-guidelines-oxygen-generators-and-oxygen-equipment-emergency-use

Background:
Without the ability to adequately maintain the patient's airway, all other interventions are futile. Minimum airway control equipment with various sizes of airway devices appropriate to patient population within the practice and examples of oxygen delivery systems include:

- Wall oxygen delivery system
- Portable oxygen tank
- Portable oxygen concentrator (POC)

All oxygen delivery systems must be able to be regulated up to 6 liters of oxygen per minute, maintained for a minimum of 15 minutes. This flow rate establishes a minimum total oxygen delivery capacity of 90 liters for these devices:

- Nasal cannula or mask
- Bulb syringe
- Ambu bag as appropriate to patient population served. Mask should be replaced when they no longer make a solid seal.
- Portable oxygen tanks are maintained at least ¾ full. There is a method/system in place for oxygen tank replacement. If oxygen tanks are less than ¾ full at time of site visit, site has a back-up method for supplying oxygen if needed and a scheduled plan for tank replacement.
- Oxygen tubing does not need be connected to oxygen tank, but must be kept in close proximity to tank.

Note: Oropharyngeal airways are no longer required.

Purpose:

Ensure the appropriate monitoring and maintenance of oxygen delivery system.

Tips:

1. Locate oxygen supply in an easily accessible location.

2. **Oxygen cylinders should never be stored with pressure in the regulator or with the flowmeter set at any other value than "0".** If stored with pressure in the regulator, the integrity of the system may be compromised, and the tank could leak. A flowmeter storage value of other than "0" will also cause leakage.
3. Store oxygen tanks that are not in active use in upright stands or chained together to prevent falling and explosive discharge of contents. **Store oxygen away from flammable items.**
4. Cylinders should be visually inspected and checked for obvious wear and tear or leakage at least once monthly.
5. Connections to oxygen delivery devices should also be checked monthly.
6. Always turn your oxygen cylinder on, check for adequate volume and properly prepare your delivery device before delivering oxygen to the patient!!

Key Staff Training Opportunity:

Health care personnel at the site must demonstrate that they can turn on the oxygen tank.

Procedure:

1. Identify which cylinder you have (Figure A or B below) and determine which directions you need to follow. Direction/step numbers pertain to numbers on the figures below.

2. Check to be certain regulator is hand-tight on neck of cylinder (Figure A only).

3. Adjust flowmeter dial to "0". (If equipped with flowmeter dial.)

4. Open oxygen cylinder by turning toggle or key to the left (Figure A only). Figure B cylinder does not need to be opened.

5. Note the position of the indicator on the regulator dial. Just above or in the red area on the dial indicates the cylinder should be refilled. 500 psi or greater indicates sufficient oxygen for at least one patient use.

6. Record psi indication with date on a maintenance checklist (if available).

7. Close oxygen cylinder by turning toggle or key to the right (Figure A only).

8. Bleed pressure out of the regulator by turning the flowmeter dial to its highest possible setting (Figure A only).

9. Once the sound of pressure releasing is no longer heard, turn the flowmeter dial to "0" (Figure A only).

FIGURE A

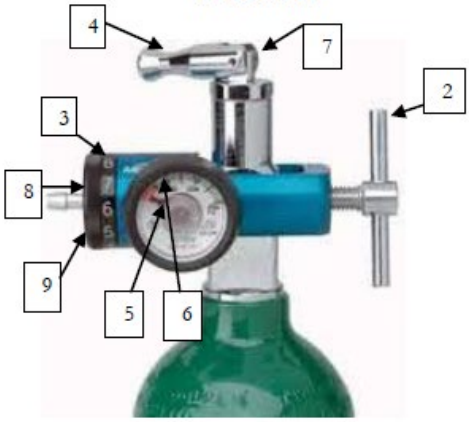
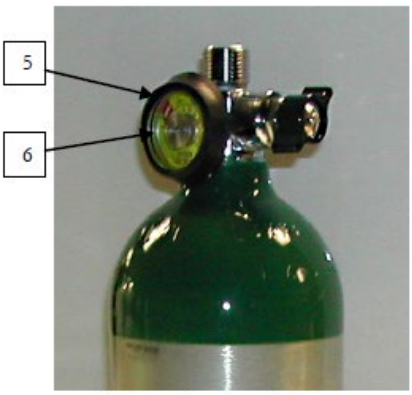


FIGURE B



(Shown without regulator)

Protocol for Medical Assistant Oxygen Tank Training

SAN FRANCISCO HEALTH PLAN
Here for you

Checklist for Medical Assistants

OBJECTIVE

The trainee will successfully demonstrate without error the performance aspects of oxygen delivery system, reading oxygen level, back-up system, and tank replacement procedure

Note: Accordance with DHCS Facility Site Review, Access and Safety, Section I, Element D, Airway Management

DATE	TRAINEE NAME	TRAINER NAME
MM/DD/YYYY		

Check Satisfactory or Unsatisfactory for each one:

Each step/action must be numbered sequentially throughout the document and be followed by outcome.

1	○ Satisfactory	○ Unsatisfactory	How to attach and change regulator on a portable unit
2	○ Satisfactory	○ Unsatisfactory	How to turn on/off a regulator
3	○ Satisfactory	○ Unsatisfactory	How to read contents gauge on a regulator
4	○ Satisfactory	○ Unsatisfactory	On our clinic's oxygen tank, which way do you turn the flow regulator knob? 
5	○ Satisfactory	○ Unsatisfactory	How to read and adjust liter flow meter on regulator
6	○ Satisfactory	○ Unsatisfactory	When and how to use back-up system
7	○ Satisfactory	○ Unsatisfactory	When to call for replacement of back-up unit and who to notify in clinic to ensure replacement is ordered
8	○ Satisfactory	○ Unsatisfactory	After turning off tank, do you have to bleed oxygen from the system before putting the oxygen back in storage area?
9	○ Satisfactory	○ Unsatisfactory	True or False: Always turn your oxygen cylinder on, check for adequate volume and properly prepare your delivery device before delivering oxygen to the patient

SFHP 2/20

Appendix A:

Laminate and affix the following to your office`s oxygen tank: CUSTOMIZE TO YOUR O2 TANK SET-UP

Oxygen tank operation

To turn on:

1. Attach oxygen delivery system to tank.
2. Turn key on top of tank in counter clockwise direction to open the flow of oxygen.
3. Read low flow regulator knob; turn in the direction the arrow indicates to increase or open. Many regulators are opposite of sink faucets, and open clockwise instead of counter-clockwise.
4. Attach oxygen delivery system to patient.

To turn off:

1. Remove oxygen delivery system from patient.
2. Turn key on top of tank in clockwise direction to shut off flow of oxygen.
3. Turn the "Low Flow" regulator knob to "open" position to bleed oxygen from the system.
4. After bleeding, gently close the "Low Flow" regulator knob.

Safety precautions for oxygen use:

(1) Never use combustibles in the presence of oxygen, including petroleum products, such as Vaseline.
(2) Do not store oxygen in temperatures over 120 degrees F.
(3) Never adjust the regulator with your body directly over the tank.
(4) Connect the tubing to the tank and adjust the regulator before placing the delivery system on the patient`s face.
(5) Do not deliver high concentrations of oxygen to patients with COPD (Chronic Obstructive Pulmonary Disease), as it may reduce their hypoxic drive, which is their only remaining stimulus to breathe.

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Reportable Diseases & Conditions
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	Title 17, California Code of Regulations (CCR) §2500, §2593, §2641-2643 and §2800-2812.
Agency/Organization Source:	San Francisco Department of Public Health, Population Health Division
Agency/Organization URL	https://www.sfcdcp.org/communicable-disease/disease-reporting/

Background:

Health care providers are legally required to report certain diseases and conditions, per California Code of Regulations. The following resource includes relevant phone and fax numbers for reporting purposes, a key list of diseases and conditions and reporting timeline guide, and a Confidential Morbidity Report Form.

Purpose:

To provide health care providers with information on reportable disease and conditions to San Francisco Department of Public Health.

Resource:

24/7 Disease Reporting Information for Clinicians

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Professional Licenses & Certifications		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	CA Business & Professional Code (BPC) §2050, §2099.5, §2506, §2725, §2746, §2835, §3500, §4110; CCR, Title 16, §1355.4, §1399.547 Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Ensure that all personnel performing parts of a specific occupation, scope of practice, are legally licensed health care professionals and who have obtained a license or certificate indicating his or her competence to practice in that field.

Definition:

A licensed health care professional (HCP) is an individual who has successfully completed a prescribed program of study in a health field and who has obtained a license or certificate indicating his or her competence to practice in that field and who are who are directly related to provision of health care services. HCP includes all paid and unpaid persons working in health-care settings. They are persons who have the potential to get themselves exposed to patients and infectious materials such as contaminated medical supplies, contaminated equipment, contaminated environmental surfaces, and contaminated air. Physicians, nurses, therapists, pharmacists, professional students and trainees, and professional contractual staff not employed with health-care facility will fall under HCP category.

- Certified Nurse Midwife (CNM)
- Certified Radiological Technologist (CRT)
- Doctor of Osteopathy (DO)
- Licensed Vocational Nurse (LVN):
- Nurse Practitioner (NP)
- Pharmacist (Pharm. D)
- Physician/Surgeon (MD)

- Physicians' Assistant (PA)
- Radiological Technician
- Registered Dietitian (RD)
- Registered Nurse (RN)

Policy:

These notices to consumers shall be evident to patients.

Note: Effective June 27, 2010, per CCR, Title 16, 1355.4, mandated by Business and Professions Code section 138, MDs (does not apply to Osteopaths) shall provide notification to each patient that states the MD(s) on site is licensed and regulated by the Board, and includes the following: NOTICE Medical doctors are licensed and regulated by the Medical Board of California (800) 633-2322 www.mbc.ca.gov.	**Note:** Effective August 11, 2011, per CCR, Title 16, 1399.547, mandated by Business and Professions Code section 138, PAs shall provide notification to each patient that states the PA(s) is licensed and regulated by the Physician Assistant Committee, and includes the following: NOTIFICATION TO CONSUMERS Physician Assistants are licensed and regulated by the Physician Assistant Committee (916) 561-8780 www.pac.ca.gov

The notice to consumers above shall be provided by one of the following methods:

- Prominently posted sign in an area visible to patients in at least 48-pt Arial font.
- A written statement signed and dated by the patient (or patient's representative) and kept in the medical record, stating the patient understands that the MD is licensed and licensed and regulated by the board (for PA's, that the PA is licensed and regulated by the PA Board).
- A statement on letterhead, discharge instructions or other document given to the patient (or patient's representative), where the notification is placed immediately above the signature line for the patient in at least 14-pt font.

Procedure:

All required professional health care licenses and certifications, issued from the appropriate California licensing/certification agency, are current and available on site or readily available when requested by reviewer.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

Appendix A

II. Personnel Standards		
Medical Professional	**License/Certification**	**Issuing Agency**
Certified Nurse Midwife (CNM)	RN License & Nurse-Midwife Certificate. Drug Enforcement Agency (DEA) Registration, *if appropriate*	CA Board of Registered Nursing DEA
Certified Radiological Technologist (CRT)	CRT Certificate.	California Department of Public Health (CDPH), Radiologic Health Branch
Doctor of Osteopathy (DO)	Physician's & Surgeon's Certificate DEA Registration	Osteopathic Medical Board of CA DEA
Licensed Midwife (LM)	Licensed Midwife Certificate. Drug Enforcement Agency (DEA) Registration, *if appropriate*	Medical Board of CA DEA
Licensed Vocational Nurse (LVN):	LVN License	CA Board of Vocational Nursing and Psychiatric Technicians
Nurse Practitioner (NP)	RN License w/NP Certification & Furnishing Number DEA Registration, *if appropriate*	CA Board of Registered Nursing DEA
Pharmacist (Pharm. D)	Pharmacist License	CA State Board of Pharmacy
Physician/Surgeon (MD)	Physician's & Surgeon's Certificate DEA Registration	Medical Board of CA DEA
Physicians' Assistant/ Associate (PA)	PA License DEA Registration, *if appropriate*	Physician Assistant Examining Committee/Medical Board of CA DEA
Radiological Technician	Limited Permit	CDPH, Radiologic Health Branch
Registered Dietitian (RD)	RD Registration Card	Commission on Dietetic Registration
Registered Nurse (RN)	RN License	CA Board of Registered Nursing
Note: All medical professional licenses and certifications must be current and issued from the appropriate agency for practice in California, and available on site. Although sites with centralized personnel departments are not required to keep documents or copies on site, copies and/or lists of currently certified or credentialed personnel must be readily available when requested by reviewers.		

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SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Notice of Provider Licensing
Facility Site Review Source:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	CCR, Title 16, 1355.4; CCR, Title 16, 1399.547
Agency/Organization Source:	Medical Board of California; Physician Assistant Board
Agency/Organization URL	www.mbc.ca.gov; https://www.pab.ca.gov/

Background:

The notice to consumers above shall be provided by one of the following methods:

- Prominently posted sign in an area visible to patients in at least 48-pt Arial font.
- A written statement signed and dated by the patient (or patient's representative) and kept in the medical record, stating the patient understands that the MD is licensed and licensed and regulated by the board (for PA's, that the PA is licensed and regulated by the PA Board).
- A statement on letterhead, discharge instructions or other document given to the patient (or patient's representative), where the notification is placed immediately above the signature line for the patient in at least 14-pt font.

Purpose:

All required professional licenses and certifications, issued from the appropriate licensing/certification agency, are current.

Resources: (Also found on SFHP website - FSR Resources)

Resource 1: Notice to Consumers - Medical Doctors

http://www.mbc.ca.gov/Download/Documents/notice-to-consumers-regulation-sample-sign.pdf

Resource 2: Notice to Consumers - Physician Assistants

https://pab.ca.gov/consumers/notice.pdf

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NOTICE TO CONSUMERS

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

(800) 633-2322

www.mbc.ca.gov

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.

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

Physician Assistants are licensed and regulated by the Physician Assistant Board

(916) 561-8780

www.pab.ca.gov

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Personnel Identification Badges		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL BPC §680		

Purpose:

Health care personnel are properly identified.

Definition:

Health care practitioner means any person who engages in acts that are the subject of licensure or regulation under the CA B&P Code (Section 680-681).

Policy:

- Health care personnel shall disclose, while working, their name and title on a name tag at least 18-point type.
- It is acceptable for health care personnel in a practice or an office, whose license is prominently displayed, to opt not to wear a nametag.

Notes:

- In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title "nurse" in reference themselves, in any capacity, except for an individual who is a registered nurse, or a licensed vocational nurse.
- "Health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under Business and Professions Code (Sections 680-681). If a health care practitioner or licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, the employing entity or agency shall have the discretion to make an exception from the nametag requirement for the individual safety or therapeutic concerns.
- In identifying medical assistants, using the phrase "Certified Medical Assistant®," or the initialisms "CMA (AAMA)®" or "CMA," to describe a medical assistant who has not been awarded or has not maintained currency of the CMA (AAMA) credential from the Certifying Board of the American Association of Medical Assistants (AAMA) is both incorrect and a matter of intellectual property law (AAMA).

- If a health care practitioner or licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, the employing entity or agency shall have the discretion to make an exception from the name tag requirement for the individual safety or therapeutic concerns.

Procedure:

18-point type

Example

1. Health care personnel shall wear a clearly legible identification badge at least one inch by three inches in size bearing the person's first name at a minimum and staff position.
2. ID badges should always be worn in a visible place above the waist so that patients can differentiate between staff and the public.
3. ID badges should be kept clean (i.e.: no stickers or other appearance altering items may be placed covering the ID badge).
4. ID badges may be worn on a standard collar clip or on a lanyard.

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Non-licensed Personnel Education and Training		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL CA B&P Code §2069; 16 CCR §1366; 22 CCR §75034, §75035		

Purpose:

Site personnel are qualified and trained for assigned responsibilities.

Definition:

Unlicensed personnel: Medical assistants (MA) are unlicensed health personnel, at least 18 years of age, who perform basic administrative, clerical, and non-invasive routine technical supportive services under the supervision of a licensed physician, surgeon or podiatrist in a medical office or clinic setting.

Supervision means the licensed physician must be physically present in the treatment facility during the performance of authorized procedures by the MA.

Policy:

The supervising physician is responsible for determining the training content and ascertaining proficiency of the MA. Training documentation maintained on site for the MA must include the following:

A) Diploma or certification from an accredited training program/school, or

B) 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.

Procedure:

1. Only qualified/trained personnel retrieve, prepare or administer medications.
2. Only qualified/trained personnel operate medical equipment.

3. Documentation of education/training for non-licensed medical personnel is maintained on site

Note: Training may 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.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Scope of Practice Policy: Standardized Procedures Agreement, Delegation of Services Agreement and Supervisory Guidelines Protocol for Non-Physician Medical Practitioners (NPMP)		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 16 CCR §1379, §1399.540, §1399.545, §1474; BPC §2725, §2746.5, §2746.51, §2836.		

Purpose:

The scope of practice for Nurse Practitioners (NP), Certified Nurse Midwives (CNM), and Physician Assistants (PA) are clearly defined including the delegation of the supervision of MAs when supervising physician is off premises.

Definitions:

- Non-physician medical practitioners (NPMP): A Nurse Practitioner (NP), Physician Assistant (PA), or nurse midwife authorized to provide primary care under physician supervision.
- Certified Nurse Midwives (CNM): A certified nurse-midwife (CNM) is a registered nurse who is a graduate of a Board-approved nurse midwifery program and who possesses evidence of certification issued by the California Board of Registered Nursing. A certified nurse-midwife may be known as an Advanced Practice Registered Nurse in accordance with Business and Professions Code Section 2725.5. Nurse-midwifery practice as conducted by CNMs is the independent, comprehensive management of women's health care in a variety of settings focusing particularly on pregnancy, childbirth, and the postpartum period. It also includes care of the newborn, and the family planning and gynecological needs of women throughout the life cycle[i].
- Nurse Practitioners (NP): "Nurse practitioner" means a registered nurse who possesses additional preparation and skills in physical diagnosis, psycho-social assessment, and management of health-illness needs in primary health care, and who has been prepared in a program conforms to board standards as specified in 16 CCR Section 1484[ii].

- Physician Assistants (PA): The scope of a given PA's practice is limited by his/her supervising physician. Whatever medical specialty a physician practices (e.g., general practice, family medicine, internal medicine, etc.) limits the PA's scope of practice. The Delegation of Services Agreement between the PA and the supervising physician then further defines exactly what tasks and procedures a physician is delegating to the PA. These tasks and procedures must be consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition[iii].
- Supervising physician – Identifies 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.

Policy:

Physician offices will have standardized procedures that clearly define the scope of services and supervision of all non-physician medical providers (NPMP). Documents outlining scope of practice for each NPMP are accessible on site and made available upon request. CNMs and NPs operate under written Standardized Procedures, while PAs operate under a Practice Agreement or Delegation of Services Agreement.

Procedure:

I. Supervision of Non-Physician Medical Practitioners

A. The supervising physician holds ultimate responsibility for the practice of each supervised non- physician medical practitioner.

1. A licensed physician and surgeon oversee the activities of, and accept responsibility for, the medical services rendered by a PA.

2. Supervising or back-up physician is available in person or by electronic communication at all times when a NPMP is caring for patients.

B. The number of non-physician medical practitioners who may be supervised by a single primary care physician is limited to the full-time equivalent of one of the following:

1. 4 nurse practitioners with furnishing license,

2. 4 certified nurse midwives, 4 physician's assistants, or

3. 4 of the above individuals in any combination which does not exceed the limit stated.

C. A primary care physician, an organized outpatient clinic or a hospital outpatient department cannot utilize more non-physician medical practitioners than can be supervised within these stated limits.

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

E. Standardized Procedures for NP or CNM should identify the furnishing of drugs or devices, extent of physician or surgeon supervision, method of periodic review of competence, including peer review, and review of provisions in the Standardized Procedures.

F. Standardized Procedures shall undergo established periodic review, with signed, dated revisions completed at each change in scope of work.

G. Evidence of supervision of NPMP(s) are verifiable through on-site observation of supervisory processes, documentation, or supervisor/NPMP's knowledge of the process.

II. Certified Nurse Midwife (CNM)

A. The certificate to practice nurse-midwifery authorizes the holder, under supervision of a licensed physician or surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family planning care for the mother, and immediate care for the newborn.

B. The supervising and back-up physician or surgeon for the CNM must be credentialed to perform obstetrical care in the same delivering facility in which the CNM has delivery privileges.

III. Nurse Practitioner (NP)

A. NPs are prepared through education and experience to provide primary care and to perform advanced procedures.

B. The extent of required supervision must be specified in the Standardized Procedures.

C. Standardized procedures legally define the expanded scope of nursing practice that overlaps the practice of medicine.

D. Standardized Procedures should identify the furnishing of drugs or devices, extent of physician or surgeon supervision, method of periodic review of competence, including peer review, and review of provisions in the Standardized Procedures.

IV. Physician Assistant (PA)

A. Practice Agreement:

a. Defines specific procedures identified in practice protocols or specifically authorized by the supervising physician, and must be dated and signed by physician and PA.

b. The delegation of the supervision of MAs when supervising physician is off premises.

c. An original or copy must be readily accessible at all practice sites in which the PA works.

d. Failure to maintain a Practice Agreement is a violation of the PA Regulations and is grounds for disciplinary action by the Medical Board of California against a physician assistant's licensure.

B. Supervising Physician's Responsibility for Supervision of PAs' Practice Agreement: Defines supervision responsibilities and methods required by Title 16, section 1399.545 of the Physician Assistant Regulations, and is signed by the physician. The following procedures must be identified:

a. Emergency transport of patients and back-up procedures (e.g., can call 911, name of hospital to transport patient included in Practice Agreement) for when the supervising physician is not on the premises

First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date

[i] https://www.rn.ca.gov/pdfs/regulations/npr-b-31.pdf

[ii] https://www.rn.ca.gov/pdfs/regulations/bp2834-r.pdf ; CA Bus & Prof Code § 2836 (ARTICLE 8. Nurse Practitioners [2834 - 2837]); Section 1484. (16 Code Cal. Rules 1480 (a))

[iii] https://www.mbc.ca.gov/Licensees/Physicians_and_Surgeons/Physician_Assistants_FAQ.aspx ; Business & Professions Code 3516(b); W & I Code 14132.966

DELEGATION OF SERVICES AGREEMENT
BETWEEN
A SUPERVISING PHYSICIAN AND A PHYSICIAN ASSISTANT

Title 16, Section 1399.540 of the Physician Assistant Regulations states, in part, “a) A physician assistant may only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant’s education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant. b) The writing which delegates the medical services shall be known as a delegation of services agreement. A delegation of services agreement shall be signed and dated by the physician assistant and each supervising physician. A delegation of services agreement may be signed by more than one supervising physician only if the same medical services have been delegated by each supervising physician. A physician assistant may provide medical services pursuant to more than one delegation of services agreement.”

The following document is a sample Delegation of Services Agreement (DSA) to assist you with meeting this legal requirement. This sample DSA is provided for information purposes; feel free to duplicate or modify it as appropriate and consistent with the law.

If you choose not to use the sample DSA, please be aware that you are still required by law to execute a DSA with your supervising physician. The DSA must be signed and dated by you and your supervising physician. The original or a copy of this document should be maintained at all practice sites where the physician assistant practices, and should be readily accessible. It is recommended that you retain prior DSAs for one to three years after the DSA is no longer current or valid.

While every practicing physician assistant is required to have a DSA, you are **not** required to submit it to the Physician Assistant Board. If requested, you must make a copy of your DSA available to any authorized agent of the Medical Board of California, the Osteopathic Medical Board of California, or the Physician Assistant Board who may request it.

Failure to have a current DSA constitutes a violation of the Physician Assistant Regulations and is grounds for disciplinary action against a physician assistant’s license. In addition, failure by the physician assistant and supervising physician to comply with the supervision requirements specified in the Physician Assistant Regulations and in the Delegation of Services Agreement is ground for disciplinary action.

THE ATTACHED DOCUMENTS DO NOT NEED TO BE RETURNED TO THE PHYSICIAN ASSISTANT BOARD

SAMPLE

DELEGATION OF SERVICES AGREEMENT BETWEEN SUPERVISING PHYSICIAN AND PHYSICIAN ASSISTANT (Title 16, CCR, Section 1399.540)

PHYSICIAN ASSISTANT_____
(Name)

Physician assistant, graduated from the _____
(Name of PA Training Program)

physician assistant training program on _____.
(Date)

He/she took (or is to take) the licensing examination for physician assistants recognized by the State of California (e.g., Physician Assistant National Certifying Examination or a specialty examination given by the State of California) on _____.
(Date)

He/she was first granted licensure by the Physician Assistant Board on _____, which expires on _____, unless renewed.
(Date) (Date)

SUPERVISION REQUIRED. The physician assistant named above (hereinafter referred to as PA) will be supervised in accordance with the written supervisor guidelines required by Section 3502 of the Business and Professions Code and Section 1399.545 of the Physician Assistant Regulations. The written supervisor guidelines are incorporated with the attached document entitled, "Supervising Physician's Responsibility for Supervision of Physician Assistants."

AUTHORIZED SERVICES. The PA is authorized by the physician whose name and signature appear below to perform all the tasks set forth in subsections (a), (b), (c), (d), (e), (f), (g) and (h) of Section 1399.541 of the Physician Assistant Regulations, when acting under the supervision of the herein named physician. (In lieu of listing specific lab procedures, etc. the PA and *supervising* physician may state as follows: "Those procedures specified in the practice protocols or which the supervising physician specifically authorizes.")

The PA is authorized to perform the following laboratory and screening procedures:

_____

_____

The PA is authorized to assist in the performance of the following laboratory and screening procedures:

_____

_____

The PA is authorized to perform the following therapeutic procedures:

_____

_____

The PA is authorized to assist in the performance of the following therapeutic procedures:

_____

_____

The PA is authorized to function as my agent per bylaws and/or rules and regulations of (name of hospital):

_____

_____

a) The PA is authorized to write and sign drug orders for Schedule: II, III, IV, V without advance approval (circle authorized Schedule(s). The PA has taken and passed the drug course approved by the Board on _____ (attach certificate). DEA #:_____.
Date

or

b) The PA is authorized to write and sign drug orders for Schedule: II, III, IV, V with advance patient specific approval (circle authorized Schedule(s). DEA #:_____.

CONSULTATION REQUIREMENTS. The PA is required to always and immediately seek consultation on the following types of patients and situations (e.g., patient's failure to respond to therapy; physician assistant's uncertainty of diagnosis; patient's desire to see physician; any conditions which the physician assistant feels exceeds his/her ability to manage, etc.)

_____
(List Types of Patients and Situations)

MEDICAL DEVICES AND PHYSICIAN'S PRESCRIPTIONS. The PA may transmit by telephone to a pharmacist, and orally or in writing on a patient's medical record or a written prescription drug order, the supervising physician's prescription in accordance with Section 3502.1 of the Business and Professions Code.

The supervising physician authorizes the delegation and use of the drug order form under the established practice protocols and drug formulary. _____ YES _____ NO

The PA may also enter a drug order on the medical record of a patient at _____
(Name of Institution)
in accordance with the Physician Assistant Regulations and other applicable laws and regulations.

Any medication handed to a patient by the PA shall be authorized by the supervising physician's prescription and be prepackaged and labeled in accordance with Sections 4076 of the Business and Professions Code.

PRACTICE SITE. All approved tasks may be performed for care of patients in this office or clinic located at _____ and, in _____ hospital(s) and
(Address / City) (Address / City)
_____ skilled nursing facility (facilities) for care of
(Name of Facility)
patients admitted to those institutions by physician(s) _____ .
(Name/s))

EMERGENCY TRANSPORT AND BACKUP. In a medical emergency, telephone the 911 operator to summon an ambulance.

The _____ emergency room at _____
(Name of Hospital) (Phone Number)
is to be notified that a patient with an emergency problem is being transported to them for immediate admission. Give the name of the admitting physician. Tell the ambulance crew where to take the patient and brief them on known and suspected health condition of the patient.
Notify _____ at _____ immediately
(Name of Physician) (Phone Number/s))
(or within _____ minutes).

PHYSICIAN ASSISTANT DECLARATION
My signature below signifies that I fully understand the foregoing Delegation of Services Agreement, having received a copy of it for my possession and guidance, and agree to comply with its terms without reservations.

_____ _____
Date Physician's Signature (Required)

_____
Physician's Printed Name

_____ _____
Date Physician Assistant's Signature (Required)

_____
Physician Assistant's Printed Name

SAMPLE ONLY

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Physician Assistant Delegation of Services Agreement
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.)
Agency/Organization Source:	Physician Assistant Board
Agency/Organization URL	https://pab.ca.gov/

Background:

Physician Assistants (PA): Every PA is required to have the following documents:

1) Delegation of Services Agreement: 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. There is no established time period for renewing the Agreement, but it is expected that the Agreement will be revised, dated and signed whenever any changes occur. Failure to maintain a 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.
2) Approved Supervising Physician's Responsibility for Supervision of Physician Assistants Agreement: Defines supervision responsibilities and methods required by Title 16, section 1399.545 of the Physician Assistant Regulations, and is signed by the physician. The following procedures must be identified:
    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.
    d. Responsibility of the PA to enter the

Drug Enforcement Agency (DEA): Each NP, CNM, and PA that prescribes controlled substances is required to have a valid DEA Registration Number.

Purpose: To define scope of practice for Physician Assistants and outline the delegation of services between a supervising physician and a physician assistant.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
BOARD OF REGISTERED NURSING
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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 _____

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Resource Guide

Subject:	Standardized Procedures Agreement (NP & CNM)
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.)
Agency/Organization Source:	Board of Registered Nursing
Agency/Organization URL	https://www.rn.ca.gov/pdfs/regulations/npr-b-20.pdf

Background:

Certified Nurse Midwives (CNM): The certificate to practice nurse-midwifery authorizes the holder, under supervision of a licensed physician or surgeon, to attend cases of normal child-birth and to provide prenatal, intrapartum, and postpartum care, including family planning care for the mother, and immediate care for the newborn. The supervising and back-up physician or surgeon for the CNM must be credentialed to perform obstetrical care in the same delivering facility in which the CNM has delivery privileges.

Nurse Practitioners (NP): Nurse practitioners are prepared through education and experience to provide primary care and to perform advanced procedures. The extent of required supervision must be specified in the Standardized Procedures.

Drug Enforcement Agency (DEA): Each NP, CNM, and PA that prescribes controlled substances is required to have a valid DEA Registration Number.

Purpose: To define the scope of practice for non-physician medical practitioners

Resource: See PDF in library- An Explanation of Standardized Procedure Requirements for Nurse Practitioner Practice

EVIDENCE OF STAFF TRAINING

Employee's Name: _____ Date of Hire: _____

Employee's Position: _____ License Number: _____

Trainer or Learning Management System (LMS): _____

Annual Trainings

Topic	Brief description of training content	Training Dates			
Infection Control & Universal Precautions					
Blood Borne Pathogens Exposure Prevention					
Biohazardous Waste Handling					

Trainings Upon Hire (and as needed)

Topic	Brief description of training content	Training Date
Fire Safety & Prevention		
Non-Medical Emergency Procedures: natural disaster (e.g. earthquakes), workplace violence, etc.		
Medical Emergency Procedures & Action Plan		
Patient Confidentiality		
Informed Consent, including Human Sterilization		
Prior Authorization Requests		
Grievance/Complaint Procedure		
Child, Elder, Domestic Violence Abuse		
Sensitive Services/Minors' Rights		
Health Plan Referral Process/Procedures/Resources		
Cultural & Linguistics		
Disability Rights & Provider Obligations		

Trainings as needed

Topic	Brief description of training content	Training Date
Medication Administration Methods		
Operation of Medical Equipment or Performance of Clinical Laboratory Procedures		

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SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Personnel Training: Child Abuse Reporting		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

POLICY: Health Care practitioners who have knowledge of or observe a child, in his or her Professional capacity or within the scope of his or her employment, whom he or she knows or reasonably suspects, has been the victim of child abuse or neglect shall report the suspected incident of abuse or neglect to a "child protective agency".

PROCEDURE:

I. Reporting

A. The report must be made to a "child protective agency". A child protective agency is a county welfare or probation department or a police or sheriff's department (P.C. 11165.9, P.C. 11166[a])

1. Written reports must be submitted on a Department of Justice form - Form SS 8572 (DOJ SS 8572) which can be requested from your local child protective agency
2. A report must be made immediately (or as soon as possible) by phone
3. A written report must be forwarded to the child protective agency within 36 hours of receiving the information regarding the incident
4. A single report may be made if two or more persons have knowledge of suspected child abuse or neglect
5. Have the following information ready to report:
   - Name of reporter
   - Name and present location of the child
   - Nature and extent of the injury, and any evidence of prior abuse
   - Any other information, including what led you to suspect child abuse, if requested by the child protective agency (P.C. § 11167 [a])

6. Failure to make a required report is a misdemeanor punishable by up to six months in jail and/or up to a $1,000 fine (P.C. 1172[e]). Persons who fail to report can also be subject to a civil lawsuit, and found liable for damages, especially if the child-victim or another child is further victimized because of the failure to report

II. Indicators of Abuse

A. Physical Abuse

1. Physical Indicators of Physical Abuse

• Fractures, lacerations, bruises that cannot be explained, or explanations which are improbable given the extent of the injury

• Burns (cigarette, rope, scalding water, iron, radiator)

• Infected burns, indicating delay in seeking treatment

• Facial injuries (black eyes, broken jaw, broken nose, bloody nose, bloody or swollen lips) with implausible or nonexistent explanations

• Subdural hematomas, long-bone fractures, fracture in different states of healing

• Pattern of bruising (e.g., parallel or circular bruises) or bruises in different stages of discoloration, indicating repeated trauma over time 2. Behavioral Indications of Physical Abuse

• Hostile, aggressive, verbally abusive towards others

• Fearful or withdrawn behavior

• Self-destructive (self-mutilates, bangs head, etc.)

• Destructive (breaks windows, sets fires, etc.)

• Out-of-control behavior (seems angry, panics, easily agitated)

• Frightened of going home, frightened of parents/caretakers or, at the other extreme, is overprotective of parent(s) or caretaker(s)

• Attempts to hide injuries; wears excessive layers of clothing, especially in hot weather

• Difficulty sitting or walking

• Clingy, forms indiscriminate attachments

• Apprehensive when other children cry

• Wary of physical contact with adults

• Exhibits drastic behavioral changes in and out of parental/caretaker presence

• Suffers from seizures or vomiting

• Exhibits depression, suicide attempts, substance abuse, or sleeping and eating disorders

B. Sexual Abuse

1. Physical Indicators of Sexual Abuse; the following may be indicative of sexual abuse:

• Wears torn, stained, or bloody underclothing

• Physical trauma or irritation to the anal/genital area (pain, itching, swelling, bruising, bleeding, laceration, abrasions), especially if injuries are unexplained or there is an inconsistent explanation

• Knowledge of a child's history of previous or recurrent injuries/diseases

• Swelling or discharge from vagina/penis

- Visible lesions around mouth or genitals
- Complaint of lower abdominal pain
- Painful urination, defecation
- Sexually transmitted diseases
- Difficulty in walking or sitting due to genital or anal pain
- Psychosomatic symptoms (stomachaches, headaches)

2. Behavioral Indicators of Sexual Abuse

- Sexualized behavior (has precocious knowledge of explicit sexual behavior and engages self or others in overt or repetitive sexual behavior)
- Compulsive indiscreet masturbation
- Excessive curiosity about sexual matters or genitalia (self or others)
- Unusually seductive with classmates, teachers, and other adults
- Excessive concern about homosexuality, especially by boys

3. Behavioral Indicators of Sexual Abuse in Younger Children; the following may be exhibited by younger children who are experiencing sexual abuse:

- Wetting pant, bed wetting or fecal soiling
- Eating disturbances such as overeating, under eating
- Fears or phobias
- Compulsive behavior
- School problems or significant change in school performance (attitude and grades)
- Age-inappropriate behavior, including pseudo maturity or regressive behavior such as bed wetting or thumb sucking
- Inability to concentrate
- Drastic behavior changes
- Speech disorders
- Frightened of parent/caretaker or of going home

4. Behavioral Indicators of Sexual Abuse in Older Children and Adolescents; the following are behaviors that may be exhibited by older children and adolescents who are experiencing sexual abuse:

- Withdrawal, clinical depression, apathy, chronic fatigue
- Overly compliant behaviors
- Poor hygiene or excessive bathing
- Poor peer relations and social skills; inability to make friends; nonparticipation in sports and social activities
- Acting out; running away; aggressive, antisocial, or delinquent behavior
- Alcohol or drug abuse
- Prostitution or excessive promiscuity
- School problems, frequent absences, sudden drop in school performance
- Refusal to dress to physical education

• Fearfulness of showers or restrooms; of home life, as demonstrated by arriving at school early or leaving late; of going outside or participating in familiar activities; of males (in cases of male perpetrator and female victim)

• Self-consciousness of body beyond that expected for age

• Sudden acquisition of money, new clothes, or gifts with no reasonable explanation

• Suicide attempt, self-mutilation, or other-destructive behavior

• Crying without provocation

• Setting fires

• Pseudo-mature (seems mature beyond chronological age)

• Eating disorders

C. Neglect

1. Physical Indicators of Neglect; Neglect may be suspected when one or more of the following conditions exist:

• Failure to thrive-the child fails to gain weight at the expected rate for a normal child

• Malnutrition or poorly balanced diet (bloated stomach, extremely thin, dry, flaking skin, pale, fainting)

• Inappropriate dress for weather

• Dirty unkempt, extremely offensive body odor

• Unattended medical or dental conditions (e.g., infections, impetigo)

• Evidence of poor or inadequate supervision for the child's age

2. Behavioral Indicators of Neglect

• Clingy or indiscriminate attachment

• Depressed, withdrawn, or apathetic

• Antisocial or destructive behavior

• Fearfulness

• Substance abuse

• Speech, eating, or habit disorders (biting, rocking, whining)

• Often sleepy or hungry

• Brings only candy, chips, and soda for lunch or consistently "forget" to bring food

III. Definitions

A. Physical abuse: characterized by physical injury (for example, bruises and fractures) resulting from punching, beating, kicking, biting, burning, or otherwise harming a child. Any injury resulting from physical punishment that requires medical treatment is considered outside the realm of normal disciplinary measures.

B. Neglect: the negligent treatment or the maltreatment of a child by a person Responsible for the child's welfare under circumstances indicating harm or threatened harm to the child's health or welfare. The term includes both acts and omissions on the part of the responsible person.

C. Severe neglect: the negligent failure of a person having the care or custody of a child to protect the child from severe malnutrition or medically diagnosed nonorganic failure to thrive. "Severe neglect" also means those situations of neglect where any person having the care or custody of a child willfully causes or permits the person or health of the child to be placed

in a situation such that his or her person or heath is endangered, including the intentional failure to provide adequate food, clothing, shelter, or medical care.

D. Sexual abuse: refers to sexual assault or sexual exploitation

1. Sexual assault includes rape, statutory rape, rape in concert, incest, sodomy, and lewd or lascivious acts upon a child, oral copulation, sexual penetration, or child molestation. It includes, but is not limited to, all of the following:

- Any penetration, however slight, of the vagina or anal opening of one person by the penis of another person, whether or not there is the emission of semen
- Any sexual contact between the genitals or anal opening of one person and the mouth or tongue of another person
- Any intrusion by one person into the genital or anal opening of another person, including the use of any object for this purpose, excepting acts performed for a valid medical reason
- The intentional touching of the genitals or intimate parts (including the breasts, genital area, groin, inner thighs, and buttocks) or the clothing covering them, of a child, or of the perpetrator by a child, for purposes of sexual arousal or gratification, excepting acts that may reasonably be construed to be normal caretaker responsibilities; interaction with, or demonstrations of affection for, the child; or acts performed for a valid medical purpose
- The intentional masturbation of the perpetrator's genitals in the presence of a child (P.C. 11165.1[b])

2. Sexual exploitation refers to any of the following:

- Depicting a minor engaged in obscene acts in violation of law; preparing, selling, or distributing obscene matter that depicts minors; employment of minor to perform obscene acts
- Any person who knowingly promotes, aids, or assists, employs, uses, persuades, induces, or coerces a child, or any person responsible for a child's welfare, who knowingly permits or encourages a child to engage in, or assists other to engage in, prostitution or a live performance involving obscene sexual conduct, or to either pose or model alone or with others for purposes of preparing a film, photograph, negative, Slide, drawing, painting, or other pictorial depiction, involving obscene Sexual conduct. "Person responsible for a child's welfare" means a parent, guardian, foster parent, or a licensed administrator or employee of a public or private residential home, residential school, or other residential institution
- Any person who depicts a child in, or who knowingly develops, duplicates, prints or exchanges, any film, photograph, video tape, negative, or slide in which a child is engaged in an act of obscene sexual conduct, except for those activities by law enforcement and prosecution agencies and other persons described in subdivisions {c) and (e) of Section 311.3 (P.C. 11165.1[c])

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

Appendix A: Suspected Child Abuse Report
https://oag.ca.gov/sites/all/files/agweb/pdfs/childabuse/ss_8572.pdf

Appendix B: How to report abuse in San Francisco County

☎(800) 856-5553 FCS Hotline, 24 hours a day, 7 days a week

Mandated reporters must submit a completed Suspected Child Abuse Report (SCAR) form within 36 hours of the verbal report to the hotline via one of the following:

•Fax: (415) 557-5351
•Mail:
Family & Children's Services
Attn: Hotline #110
P.O. Box 7988
San Francisco, CA 94120-7988
•Email: hsafcserfax@sfgov.org

Appendix C: How to report abuse in San Mateo County

Child Abuse and Neglect Hotline
☎ 650-802-7922 or
☎ 800-632-4615
If a child is in immediate danger, please call 911.
•Email: HSA_ScreeningUnit@smcgov.org

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.

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Personnel Training: Elder Abuse Reporting		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL Welfare and Institutions Code§ 15630		

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

A. Reports must be made both by telephone and in writing

1. A telephone report must be made immediately or as soon as practically possible
2. A written report is to be made within two working days using the SOC341, "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.0. Box 980788

West Sacramento, Ca 95798-078

Fax: 916-371-3518

3. All of the following types of abuse must be reported:

- Physical abuse (including sexual abuse)
- Abandonment
- Isolation
- Abduction
- Financial abuse
- Neglect (including self-neglect)

4. 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

5. 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

6. 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

7. 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 y both imprisonment and fine

8. A single report may be made when two or more persons have knowledge of a suspected instance of abuse

II. Exceptions to Reporting Requirement

A. There are exceptions to the requirement to report:

1. Reporter is not aware of any independent evidence that corroborates the statement that the abuse has occurred

2. 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 mental illness or dementia

3. The reporter reasonably believes that the abuse did not occur

III. Possible Indicators of Abuse or Neglect

A. Physical Signs

1. Injury that has not been cared for properly
2. Injury that is inconsistent with explanation for cause
3. Pain from touching
4. Cuts puncture wounds, burn, bruises, and welts
5. Dehydration or malnutrition without illness-related cause
6. Poor coloration
7. Sunken eyes or cheeks
8. Inappropriate administration of medication
9. Soiled clothing or bed
10. Frequent use of hospital or health care/doctor shopping
11. Lack of necessities such as food, water, or utilities
12. Lack of personal effects, pleasant living environment, and personal items
13. Forced isolation

B. Behavioral Signs

1. Fear
2. Anxiety, agitation
3. Anger
4. Isolation, withdrawal
5. Depression
6. Non-responsiveness, resignation, ambivalence
7. Contradictory statements, implausible stories
8. Hesitation to talk openly
9. Confusion or disorientation

C. Signs by Caregiver

1. Prevents elder from speaking to or seeing visitors
2. Anger, indifference, aggressive behavior toward elder
3. History of substance abuse, mental illness, criminal behavior, or family violence
4. Lack of affection toward elder
5. Flirtation or coyness as possible indicator of inappropriate sexual relationships
6. Conflicting accounts of incidents
7. Withholds affection

IV. Definitions

A. Abandonment: The desertion or willful forsaking of an elder or dependent Adult by anyone having care or custody of that person when a reasonable person would continue to provide care or custody

B. 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 conservative without the consent of the conservator or court

C. 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 is necessary to avoid harm or mental suffering

D. 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 mental abilities have diminished because of age as well as any 10 to 64-year-old who is admitted as an inpatient to a 24-hour health facility

E. Elder: Any person who is 65 years of age or older

F. 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

G. Goods and services includes, 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

H. 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

I. 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

J. 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

K. 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

L. 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

M. 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

Resources:

How to Report Abuse – San Francisco County

State law requires that mandated reporters immediately report cases of suspected abuse or neglect of an elder or dependent adult to Adult Protective Services (APS).

(800) 814-0009 APS Hotline, 24 hours a day, 7 days a week

- Emergencies: Call 911 if an elder or dependent adult is in immediate physical danger.
- Non-urgent, online reports: Submit a referral on reporttoaps.org.
- Urgent reports: Call the APS Hotline for an in-person response within 24 hours, followed by a written report within two business days using Form SOC 341 (English | Spanish).
- Non-urgent, verbal reports: Call the APS Hotline to make a verbal report, followed by a written report within two business days using Form SOC 341 (English | Spanish).
- Financial abuse: Financial institutions should call the APS hotline to make a verbal report, followed by a written report within two business days using Form SOC 342.

Submit Form SOC 341 or 342: Fax to (415) 355-3549, or mail to

P.O. Box 7988
SF, CA 94120-7988
Attn: APS.

Questions? Call the APS Hotline to speak with an APS Integrated Intake Social Worker.

How to Report Abuse – San Mateo County

1. Call the TIES Line at 1-800-675-8437 to report suspected abuse or neglect
2. Complete the SOC 341 or SOC 342 Form and fax to 1-833-817-7482
3. SOC 341 and SOC 342 Forms can also be reported online via DocuSign at https://www.smchealth.org/elderabuse

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SOC 341 Form – Suspected Dependent Adult/Elder Abuse

https://cdss.ca.gov/MandatedReporting/story_content/external_files/SOC341.pdf

SOC 342 Form – Financial Abuse

https://www.cdss.ca.gov/cdssweb/entres/forms/English/soc342.pdf

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

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.

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Personnel Training: Domestic Violence Reporting		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL Penal Code Section 11160 et. seq		

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

A. Reports must be made both by telephone and in writing to a local law enforcement agency

1. A telephone report must be made immediately or as soon as practically possible

2. A written report is to be made within two working days of receiving the Information using OCJP 920: Suspicious Injury Report Form (see attachment)

3. 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 injuries
- The identity of the person who allegedly inflicted the injury

4. 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

5. Check with the local law enforcement agency of where to report if the patient was injured in another county

6. If the battered patient is a minor then the Child Abuse and Neglect Reporting Act applies. (See Child Abuse Reporting policy and procedure)

II. Medical Record

A. 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

A. 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)

B. Patient Safety

• Address directly the risk of retaliation by the batterer and discuss how 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

C. Referral

• Provide. Patient with referrals to domestic violence services

• Assist the patient in calling a domestic crisis line if willing

D. 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 one of the shelter lines to learn how to file a "Good Cause Report" which can protect them from kidnapping charges

IV. Definitions

A. 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 of spouse or cohabitant, sodomy, oral copulation and an attempt to commit any of these crimes

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

Resource 1: State of California – Cal OES 2-90: Suspicious Injury Report
https://sfgov.org/dosw/sites/default/files/OES%202-920%20and%20SF%20Supplemental%20%20Health%20Care%20Provider%20DV%20Report%20Form.pdf

Resource 2: Health Care Provider Mandatory Reporting of Domestic Violence to Law Enforcement in San Francisco
https://sfgov.org/dosw/health-care-provider-mandatory-reporting-domestic-violence-law-enforcement-san-francisco

Resource 3: Health Care Provider Mandatory Reporting in San Mateo County
https://www.smchealth.org/sites/main/files/file-attachments/956108127domestic_violence_assault_form_21.pdf?1468762380

*If unable to access site, also available in FSR library

Family Violence Resources in San Francisco

June 2019

Area code 415 for all numbers unless otherwise noted

*24hr/7days/week

Police Department/District Attorney	
Emergency Police and Fire	911
Non-emergency Police (SFPD)	553-0123
District Attorney (DA)	553-1751
DA's Victim Services	553-9044
Reporting Lines for Abuse	
Adult/Elder Protective Services	355-6700/1-800-814-0009
Domestic Violence Reporting (SVU/SFPD)	553-9225
SF DHS Child Abuse Reporting	558-2650/1-800-856-5553
Crisis Intervention	
Domestic Violence	
*Asian Women's Shelter	1-877-751-0880
*La Casa de Las Madres (Hotline/Text line)	1-877-503-1850/200-3575
*National Domestic Violence Hotline	1-800-799-7233
Online chat: www.thehotline.org	
*Riley Center	255-0165
*WOMAN, Inc. (English/Spanish)	864-4722/1-877-384-3578
Sexual Assault/Sexual Violence	
Mujeres Unidas y Activas (Spanish only)	431-2526
*National Sexual Assault Hotline	1-800-656-HOPE (4673)
Online chat: www.rainn.org	
*San Francisco Women Against Rape (SFWAR)	647-RAPE (7273)
Child/Youth Crisis	
*CA Youth Crisis Line (Phone support for youth ages 12-24 and adults supporting youth)	1-800-843-5200
Online chat: www.calyouth.org	
*Comprehensive Child Crisis Services	970-3800
*Huckleberry Youth Programs	621-2929
*Larkin Street Youth Services	800-447-8223/800-669-6196
Child/Youth Trauma and Sexual Abuse	
Child and Adolescent Support, Advocacy, and Resource Center (CASARC)	206-8386
*Childhelp National Child Abuse Hotline	1-800-422-4453
*Huckleberry Youth Programs	621-2929
*La Casa de Las Madres (Teen line)	1-877-923-0700
Mental Health/Substance Abuse Crisis	
*Behavioral Health Access Center	255-3737
Comprehensive Crisis Services	970-3800
*National Helpline	1-800-662-HELP (4357)
*SF Suicide Prevention	781-0500/1-800-273-8255
Online chat: www.sfsuicide.org	
Westside Crisis Clinic	355-0311 x1220
245 11th St (Drop-in center hours: Mon-Fri 8am-6:00pm, Sat 9am-4pm, arrive 30 min before doors open to be seen that day)	
*ZSFG Psychiatric Emergency	206-8125
Elder Crisis	
*Friendship Line for the Elderly	1-800-971-0016

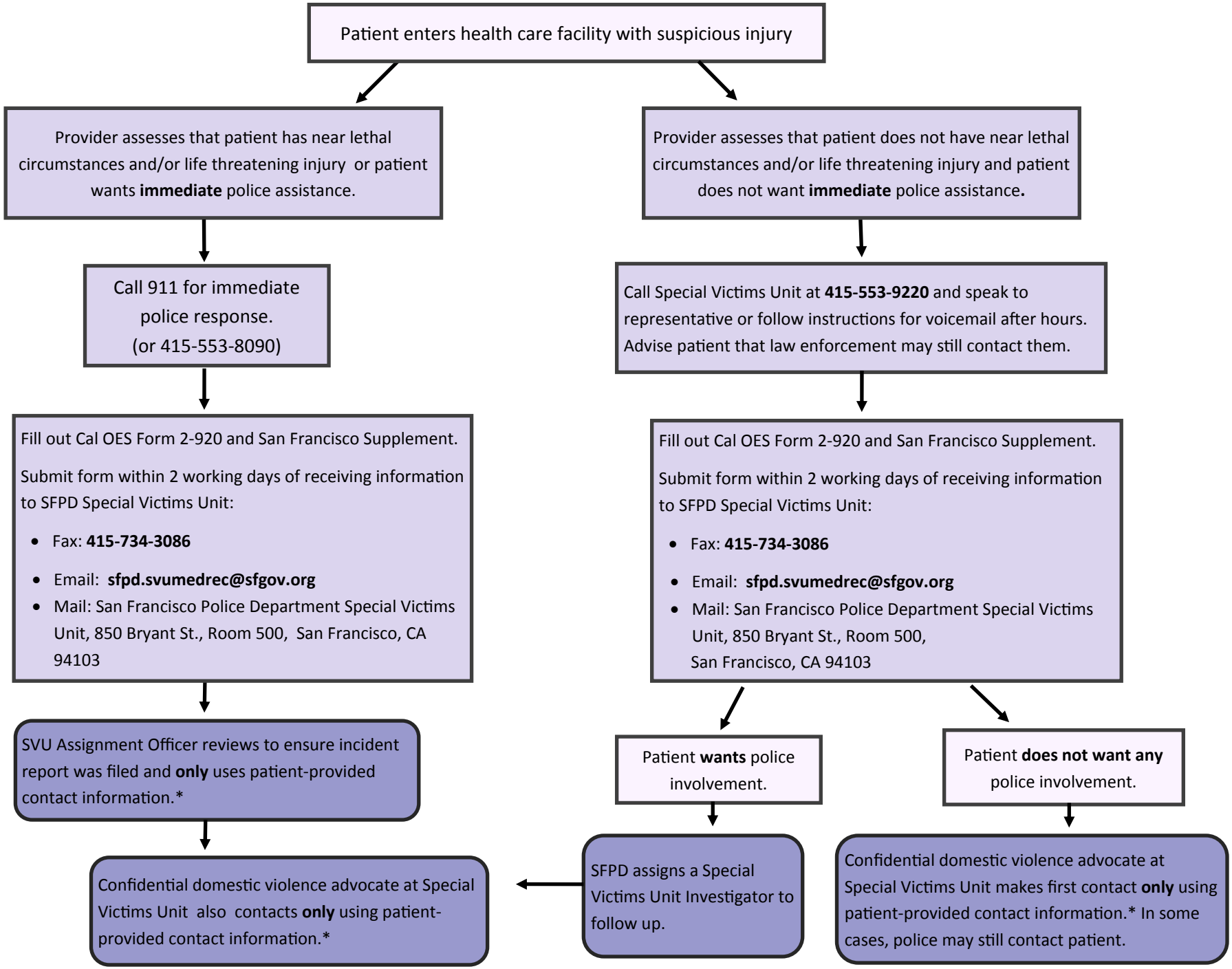
Crisis Shelters	
Domestic Violence Shelters - 3 Confidential Locations	
*Asian Women's Shelter	1-877-751-0880
*La Casa de Las Madres	1-877-503-1850
*Riley Center	255-0165
Youth Crisis Shelters	
*Huckleberry House (Shelter age 11-17)	621-2929
Larkin Street Youth Services	
*Diamond Youth Shelter (Shelter under age 17)	1-800-669-6196
*Lark-Inn for Youth (Shelter ages 18-24)	1-800-447-8223
Counseling: Resources/Referrals	
Counseling: Survivors of Domestic Violence	
Cameron House (Services for Asian communities)	781-0401
Community United Against Violence (CUAV) (Services for LGBTQ communities)	333-HELP (4357)
427 South Van Ness Avenue (Between 15th and 16th Streets) (Drop-in center and phone line hours: Wed 4-8pm)	
Glide Women's Center	674-6026
Homeless Prenatal Program	546-6756
Jewish Family & Children's Services	449-1200
*La Casa de Las Madres	1-877-503-1850
1269 Howard St (Drop-in center hours: Mon-Fri 8:30am-3:30pm)	
Mujeres Unidas y Activas (Spanish only)	431-2526
Riley Center	977-1270
1175 Howard St., "Wellness Center" building (Drop-in center hours: Mon & Thurs 9am-12pm & 1:30-4pm)	
Safe and Sound Family Support Center (Counseling and referrals for survivors/families with children age 0-6)	441-KIDS (5437)
Shalom Bayit	1-866-SHALOM-7 (1-866-742-5667)
Trauma Recovery Center	437-3000
*WOMAN, Inc.	864-4722
26 Boardman Place (Drop-in center hours: Wed (11am-12:30pm), Friday (2-3:30pm)	
Counseling: Survivors of Sexual Assault	
SF Women Against Rape (SFWAR) (Peer and group counseling)	861-2024
ZSFG Trauma Recovery/Rape Treatment Center	437-3000
Counseling: Children, Youth, and Family	
APA Family Services	617-0061
Cameron House (Services for Asian communities)	781-0401
Child Trauma Research Program (Intake line)	206-5311
Family Service Agency	474-7310
Homeless Prenatal Program	546-6756
*Huckleberry Youth Programs (Therapy age 11-21)	621-2929
Instituto Familiar de La Raza	229-0500
La Casa de Las Madres	503-0500
Larkin Street Youth Services	673-0911
Parents Place (Jewish Family & Children's Services)	359-2443
*TALKLine (Parenting support line)	441-KIDS (5437)

Counseling: Elder Services	
*Friendship Line for the Elderly	1-800-971-0016
Institute on Aging (Elder counseling referral)	750-4111
Counseling: Mental Health & Substance Use	
*Behavioral Health Access Center	255-3737
1380 Howard St (Drop in hours: Mon-Fri 8am-4:30pm)	
Counseling: Violence Perpetration	
John Hamel & Associates	472-3275
Men in Progress	674-6195
POCOVI (Spanish only)	552-1361
Resolve to Stop the Violence (RSVP)	510-268-8116
Legal Resources	
Asian Pacific Islander Legal Outreach (APILO)	567-6255
Bay Area Legal Aid (BayLegal)	354-6360/800-551-5554
Cooperative restraining Order Clinic	255-0165
Legal Aid at Work (Project Survive)	1-888-864-8335
Legal Assistance for the Elderly	538-3333
SF Bar Association (Mediation services)	782-8905
SF Bar Association (Referral line)	989-1616
Public Health Nursing (PHN)	
Home visits to high-risk prenatal/postpartum women and chronically ill children	1-800-300-9950
Bay Area Domestic Violence Resources	
Alameda County	1-510-536-7233/510-537-2552
Contra Costa County	1-888-215-5555
Marin County	924-6616/924-3456
San Mateo County	1-800-300-1080
Santa Clara County	1-408-279-2962
Solano County	1-866-487-7233
Additional Resources	
HELPLINK	211/1-800-273-6222
LEAP (Look to End Abuse Permanently)	www.leapsf.org
SF City Employee Domestic Violence Liason Program	https://sfgov.org/dosw/city-employee-domestic-violence-liaison-program
SFDPH Women & Children's Health referrals	1-800-300-9950

Electronic version: www.sfdph.org/mcah or www.leapsf.org

Changes? Email ariseproject@ucsf.edu

San Francisco Health Care Provider Reports of Suspicious Injury to Law Enforcement Flowchart



*See San Francisco Supplement to Health Practitioner Suspicious Injury Report

There are 2 steps to reporting a suspicious injury to law enforcement:

1. You must call the police.
2. You must make a written report.

The Call:

When making the call in San Francisco, you have two options:

1. Call 911 (or 415-553-8090) for immediate response:
   - if the patient has near lethal circumstances and/or life threatening injury; or
   - patient wants immediate police assistance.
2. Call the San Francisco Police Department Special Victims Unit at 415-553-9220 if neither of the above.

The Written Report:

Complete both the Cal OES Form 2-920 and San Francisco Supplement, and send to Special Victims Unit by fax, e-mail or snail mail.

Cal OES 2-920

San Francisco Supplement to Health Practitioner Suspicious Injury Report

Information You Will Be Asked by 911 Dispatcher

Is suspect at the hospital with the victim?

What is the location of the occurrence?

Victim's name

Victim medical status (if critical)

SUSPICIOUS INJURY REPORT

STATE OF CALIFORNIA
California Office of Emergency Services

Cal OES 2-920

Confidential Document

Penal Code Section 11160 requires that if any health practitioner, within their scope of their employment, provides medical services for a wound or physical injury inflicted as a result of assaultive or abusive conduct, or by means of a firearm, shall make a telephone report immediately or as soon as possible. They shall also prepare and submit a written report within 2 working days of receiving the information to a local law enforcement agency. This is the official form (Cal OES 2-920) for submitting the written report.

This form is used by law enforcement only and is confidential in accordance with Section 11163.2 of the Penal Code. In no case shall the person identified as a suspect be allowed access to the injured person's whereabouts.

Part A: PATIENT WITH SUSPICIOUS INJURY

1. Name of Patient (Last, First, Middle)	2. Birth Date	3. Gender ☐ M ☐ F	4. SAFE Telephone Number ( )

5. Patient Address (Number and Street / Apt – **No P.O. Box**) City State Zip

6. Patient Speaks English ☐ Yes ☐ No If No, identify language spoken:_____	7. Date and Time of Injury Date: Time: ☐ am ☐ pm ☐ unknown

8. Location / Address Where Injury Occurred, if Available. Check here if unknown: ☐

9. Patient description of the incident. Include any identifying information about the person the patient alleges caused the injury and the names of any persons who may know about the incident. ☐ Additional Pages Attached

10. Name of Suspect, if Identified by the Patient	11. Relationship to Patient. ☐ No Relationship

12. Suspicious Injury Description. Include a brief description of physical findings, lab tests completed or pending, and other pertinent information. ☐ Additional Pages

Part B: REQUIRED – AGENCIES RECEIVING PHONE AND WRITTEN REPORTS

13. Law Enforcement Agency Notified By Phone (Mandated by PC 11160)	14. Date and Time Reported Date: Time: am pm

15. Name of Person Receiving Phone Report (First and Last)	16. Title	17. Phone Number ( )

18. Law Enforcement Agency Receiving Written Report (Mandated by PC 11160)	19. Agency Incident Number

Part C: PERSON FILING REPORT

20. Name of Health Practitioner (First and Last)	Title	Telephone

21. Employer's Name	Phone Number

22. Employer's Address (Number and Street) City State Zip

23. HEALTH PRACTITIONER'S SIGNATURE:	26. Date Signed:

San Francisco Supplement to Health Practitioner Suspicious Injury Report

Confidential Document

Provider Instructions

1. If the patient wishes to meet with law enforcement immediately or the provider assesses that the patient has near lethal circumstances and/ or a life threatening injury, call 911.
2. For patients who do not wish to meet with law enforcement immediately or at all, and do not have near lethal circumstances and/or life threatening injury, call 415-553-9220 and speak with the Special Victims Unit representative, or follow instructions on the voicemail after hours.
3. Transmit Cal OES 2-920 and this form via fax to 415-734-3086 or via e-mail to sfpd.svumedrec@sfgov.org or via mail to San Francisco Police Department Special Victims Unit, 850 Bryant St., Room 500, San Francisco, CA 94103.

OES Form 2-920 is mandated to fulfill a health practitioner's reporting requirement under Penal Code Section 11160 et seq., whether or not the patient wishes to make a police report at the time of the initial examination. In San Francisco, we are requesting that providers complete this optional form in addition to OES Form 2-920 to improve patient care and ensure proper patient-centered follow-up

Please Note: A patient is not required to provide any information that they feel puts them at further risk.

Patient Information

Name:

Safe way(s) for police/advocate to contact the patient without the abuser/perpetrator knowing (complete all that apply):

Email:

Phone:

Alternate Contact (Friend/Family) Name and Phone:

Reason for report (check all that apply):

[ ] Firearm [ ] Assaultive or abusive conduct

a. Does the patient desire immediate contact with law enforcement (which may result in arrest of the perpetrator)?

[ ] Yes [ ] No

b. Does the patient believe police involvement would increase the risk for patient?

[ ] Yes [ ] No

c. Did you inform the patient that police may still contact them for further information?

[ ] Yes [ ] No

d. Would the patient like a follow-up call from a confidential domestic violence advocate based at the Police Department?

[ ] Yes [ ] No

e. Did you inform the patient that a confidential domestic violence advocate will attempt to contact them even if they answered "no" to question "d" above?

[ ] Yes [ ] No

Are there any special needs (i.e. disabilities) or other things that the patient wants the police or domestic violence advocate to be aware of:

_____

_____

*This form is not a substitute for complete documentation in the patient's medical record. **Never** attach a patient's medical record to this form. Consult your institution's Privacy Officer if you are unsure about whether to include certain information in the mandatory report.*

Date and Time Form Sent: _____

SAN MATEO COUNTY

REPORT OF INJURIES BY A DEADLY WEAPON OR ASSAULTIVE OR ABUSIVE CONDUCT INCLUDING DOMESTIC VIOLENCE

(Pursuant to Penal Code Section 11160 et. seq.)

NOTE TO LAW ENFORCEMENT: PATIENT'S WHEREABOUTS MUST BE DELETED FROM ANY REPORT REQUIRED TO BE DISCLOSED TO SUSPECT OR SUSPECT'S ATTORNEY.

1. PATIENT'S NAME: (if known):_____
   SEX: ☐ M ☐ F D.O.B.: ___/___/___ AGE:___ RACE/ETHNICITY: ☐ ASIAN ☐ HISPANIC
   ☐ BLACK (non-Hispanic)
   ☐ WHITE (non-Hispanic)
   ☐ PACIFIC ISLANDER ☐ FILIPINO

2. PATIENT'S WHEREABOUTS: Specify where and when patient can be safely contacted (specify any special instructions for contacting patient)_____

3. a. REASON FOR REPORT (check all that apply):
   ☐ gunshot
   ☐ knife wound
   ☐ other deadly weapon wound (specify)_____
   ☐ assaultive or abusive conduct

   b. DESCRIBE NATURE AND EXTENT OF INJURY:
   _____

   c. DATE OF INJURY (if known):
   _____

   d. LOCATION OF INJURY (city / jurisdiction):
   _____

4. a. RELATIONSHIP OF SUSPECTED PERPETRATOR TO PATIENT:
   ☐ domestic / intimate partner
   ☐ other (please specify)_____

   b. NAME OF ANYONE PATIENT ALLEGES INFLICTED THE WOUND OR INJURY:
   _____

5. IS THE PATIENT WILLING TO BE CONTACTED BY LAW ENFORCEMENT? *(NOTE: Patient must be informed that s/he may be contacted regardless of what is checked below)*
   ☐ YES ☐ NO

6. OTHER COMMENTS: (include any special needs of patient, i.e. interpreter):
   _____

7. WAS PATIENT REFERRED TO SUPPORT SERVICES?
   ☐ YES Specify_____
   ☐ NO

Law enforcement agency contacted	
Name and I.D. No. of official contacted	
Date / time of telephone report	
Health practitioner's name	
Signature / health practitioner	
Health practitioner's title	
Health practitioner's medical facility	Department
Health practitioner's phone number	Date of written report

MAIL THIS FORM TO:

_____

_____

_____
(Agency)

THIS FORM IS NOT A SUBSTITUTE FOR COMPLETE DOCUMENTATION IN THE MEDICAL RECORD.

ORIGINAL - Medical Record **YELLOW** - Health Department - Disease Control & Prevention 225 W. 37th Ave., San Mateo, CA 94403 **PINK** - Law Enforcement Jurisdiction

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Personnel Training: Informed Consent and Human Sterilization Consent		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Policy:
Site personnel receive training and/or information on member rights that include informed consent and human sterilization consent.

Procedure:

1. 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.
2. 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
    - Educational curriculum
    - Participant lists
3. Topics included in the training must include:
    a. Informed Consent for Human Sterilization

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 on Accreditation of Healthcare Organizations, Title 22, California Code of Regulations, Section 70707 and Medicare Conditions of Participation.

Requirements include and 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 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 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: 916-928-1326

Consent Form PM 330: Consent to Sterilization may be downloaded here:
https://files.medi-cal.ca.gov/pubsdoco/forms/PM-330_Eng-SP.pdf

An explanation of Consent Form PM 330 may be found here:
http://files.medi-cal.ca.gov/pubsdoco/forms/PM-330_example.pdf

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

State of California – Health and Human Services Agency

CONSENT FORM
PM 330

Department of Health Services

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

■ CONSENT TO STERILIZATION ■

I have asked for and received information about sterilization from

_____ . When I first asked for
(doctor or clinic)

the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED **PERMANENT** AND **NOT REVERSIBLE.** I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a

_____.
(Name of procedure)

The discomforts, risks and benefits associated with the operation have been explained to me. All of my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on ____/____/____.
Mo Day Yr

I, _____
Last

_____ _____
First *M. I.*

hereby consent of my own free will to be sterilized by

_____ by a
(Doctor's name)

method called _____ .
(Name of procedure)

My consent expires **180 days** from the date of my **signature below.**

I also consent to the release of this form and other medical records about the operation to:

- **Representatives of the Department of Health and Human Services.**
- **Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.**

I have received a copy of this form.

_____ *Date:* ____/____/____
Signature of individual to be sterilized *Mo Day Yr*

■ INTERPRETER'S STATEMENT ■

If an interpreter is provided to assist the individual to be sterilized: I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent

form in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

_____ *Date:* ____/____/____
Signature of Interpreter *Mo Day Yr*

PM 330 (1/99)

■ STATEMENT OF PERSON OBTAINING CONSENT ■

Before _____ signed the
(Name of Individual to be sterilized)

consent form, I explained to him/her the nature of the sterilization

operation _____, the fact that it
(Name of procedure)

is intended to be a final and irreversible procedure and the discomforts, risks, and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at anytime and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure.

_____ *Date:* ____/____/____
Signature of person obtaining consent *Mo Day Yr*

_____
Name of Facility where patient was counseled

_____
Address of Facility where patient was counseled *City* *State* *Zip Code*

■ PHYSICIAN'S STATEMENT ■

Shortly before I performed a sterilization operation upon

_____ on
(Name of individual to be sterilized)

____/____/____ *(Date of Sterilization),* I explained to him/her the nature of the
Mo Day Yr

sterilization operation _____ ,
(Name of procedure)

the fact that it is intended to be final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(**Instructions for use of Alternative Final Paragraphs**: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery when the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. **Cross out the paragraph below which is not used.**

(1) At least thirty days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (**check applicable box below and fill in information requested.**)

A Premature delivery date: ____/____/____ Individual's **expected date**
Mo Day Yr

of delivery: ____/____/____ (Must be 30 days from date of patient's signature).
Mo Day Yr

B Emergency abdominal surgery; describe circumstances: _____

_____

_____ *Date:* ____/____/____
Signature of Physician performing surgery *Mo Day Yr*

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Personnel Training: Prior Authorization / Referrals		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

To ensure that referrals for specialty care and medical procedures are processed in a timely manner, the site will have a process for the timely processing of internal and external referrals, consultant reports and diagnostic test results.

Policy:

An organized, timely referral system is clearly evident for making and tracking referrals, reviewing reports, providing/scheduling follow-up care and filing reports in medical records. Referral informational resources are readily available for use by site personnel. Site staff can demonstrate (e.g., "walk through") the office referral process from beginning to end. Systems, practices, and procedures used for handling referrals will vary from site-to-site.

Procedure:

I. Referral Forms

A. The staff has an organized, timely referral system clearly evident for making and tracking referrals, physician review of reports, and providing and/or scheduling follow-up care.

• 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. Refer to the attached 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.

• The PCP must ensure timely receipt of the specialist's report or medical procedure report. Reports must be in the patient's medical record within thirty (30) days from the date of the procedure or appointment. If the PCP site has not

received the report within 30 days, the PCP/staff will contact the specialist or procedure site to request a copy of the report.

C. PCP shall ensure that referral informational resources, i.e. Health Plan Specialty and Network Directory are readily available for use by site personnel.

The following elements should be included within the referral system:

• Patient Name

• Date of Referral

• Referral Type

• Appointment Date

• Appointment Kept or Failed

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

Resources:

SFHP page on Authorizations: https://www.sfhp.org/providers/authorizations/

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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Personnel Training - Member Grievances & Complaints		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

To establish a process for member grievances & complaints.

Definition:

• Grievance: 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.

• Complaint: 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.

Policy:

The site has an established process for member grievances and complaints.

At least one telephone number for filing grievances is posted on site or is readily available upon request. Complaint forms and a copy of the grievance procedure are readily available on site and can be provided to members promptly upon request.

Procedure:

A. The staff will 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:

1. The California Department of Managed Health Care: 1-888-HM0-2219

2. For Hearing and Speech impaired: 1-800-735-2929
3. State Fair Hearing: 1-800-952-5253
4. San Francisco Health Plan: 1-800-288-5555
5. Ombudsman: 1-888-452-8609

B. Staff will ensure that grievance forms (in threshold languages) for each participating health plan will be provided to members promptly upon request.

- The grievance form must be submitted to the health plan within 1 business day.

C. The Staff will ensure that all complaints (self-limiting complaints: e.g. service complaints, appointments wait times) are logged and submitted to the health plan monthly (if were complaints during the time period).

1. These complaints may be resolved at the point of service
2. Log the complaint and include:
    a) Date of complaint
    b) Name of complainant and ID #
    c) Nature of the complaint
    d) Resolution/action taken (include information that health plan was notified as appropriate)
    e) Date of resolution/action
    f) Date log submitted to health plan

Resource:

SFHP Grievance Information: https://www.sfhp.org/about-us/grievance-info/

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Personnel Training: Sensitive Services & Minors' Rights		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL California Law Family Code section 6922 (6920-6929) **California Law Family Code Section 6925		

Policy:

Provide medical services per California Law Family Code to protect minors' rights to sensitive services.

Procedure:

Sensitive Services/Minors Rights

- Parental consent is not required for members under the age of 18 to access pregnancy-related services, including family planning.

**California Law Family Code Section 6925.

- 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 Director of Health Services. The minor's parents or guardian are not liable for payment for medical care provided pursuant to this section.

** California Law Family Code Section 6926 (6920-6929).

- 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.

- The parents or guardian are not liable for medical care or dental care provided pursuant to this section.
- 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 minor, the whereabouts of the parent or guardian.

** California Law Family Code section 6922 (6920-6929)

- Special precautions must be taken to insure that communication regarding the medical information of a minor related to sensitive services is protected (i.e. letters and phone calls should NOT be directed to the home without the minor's authorization).

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Cultural and Linguistics Training
Facility Site Review Source:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	CLAS Standards
Agency/Organization Source:	US Department of Health and Human Services, Office of Minority Health
Agency/Organization URL	https://thinkculturalhealth.hhs.gov/

Background:

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.

Purpose:

CLAS mandates are federal requirements for all recipients of Federal fund; providers must be aware of these standards.

Resource 1: National Standards on Culturally and Linguistically Appropriate Services (CLAS)

https://www.health.pa.gov/topics/Documents/Health%20Equity/CLAS%20Standards%20FactSheet.pdf

Resource 2: Think Cultural Health

https://thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf

Resource 3: Cultural and Linguistic Services Training: SFHP Provider Network

https://www.sfhp.org/files/providers/CulturalAwarenessTraining.pdf

*Documents also available in PDF from FSR library

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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Infection Control & Universal Precautions		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

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 or HCV, and other blood borne pathogens. "Universal precautions" refer 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 towelettes 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).

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.

III. Waste Disposal Containers

A. Contaminated wastes (e.g. dental drapes, band aids, 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.

IV. Isolation Procedures

A. If you suspect that a patient may have a communicable disease you

a. Take the patient immediately to the closest exam room, place the patient in the exam room and close the door completely.

b. Immediately notify the physician or on-site practitioner of the situation and request that they see the patient as quickly as possible.

c. Wipe the reception counter down with disinfectant cleaning solution and continue seeing patients.

B. If the practitioner indicates that the patient DOES NOT have a communicable disease, clean the room as usual between patients and continue to use the room.

C. If the practitioner indicates that the patient DOES have a communicable disease

a. Follow the practitioner's directions and orders without variation.

b. If the practitioner indicates that the patient needs a mask make certain that you have put on the personnel protective gown, gloves, mask, goggles from your PPE Kit (Spill Kit)

c. Assist the patient with placing the mask on correctly and escort the patient to the closest exit door preferably not through the waiting room.

d. Keep the exam room door closed when you leave.

e. Return to the room with the necessary cleaning solution and materials and equipment. Keep the room door closed while cleaning the room.

f. Be certain to dispose of all trash, exposed disposable items, etc. in a red leak proof Biohazard bag. This includes the protective gown, mask, gloves and hair cover you are wearing while cleaning the room. Seal the bag.

g. Clean all surfaces in the room with the cleaning solution, do not wipe dry, and let the room air dry ensuring that the surfaces stay wet for the contact time indicated by the manufacturer on the container label.

h. Have a co-worker bring a second red bag to the room door and wearing gloves hold the bag open.

i. Place the bag from the room into the second bag, being careful not to touch your co-worker with the bag.

j. Your Co-worker places their gloves in the bag and closes the bag tightly and places it directly into the biohazard storage area.

k. When the contact time has been exceeded and the surfaces are dry you can open the room, remake the exam table, and continue to use the room.

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Personnel Training: Disability Rights and Provider Obligations		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL Section 504 of the Rehabilitation Act of 1973 Section 1557 of the Affordable Care Act (ACA)		

Policy:

- Site personnel have received information and/or training on patient rights and provider obligations under the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973, and/or Section 1557 of the Affordable Care Act
- Training content should include information about
    - physical access
    - reasonable accommodations
    - policy modifications, and
    - effective communication in healthcare settings.

Procedure:

1. The site has an established process for educating and training staff on patient rights and provider obligations.
    - Education and training of resources related to DHCS Medi-Cal Interpreter Services Requirements & Disability Rights
        - Interpreter Services Information
        - Cultural Awareness Training
        - SFHP Provider Manual - Key Information for Medi-Cal Providers
2. Site has Notice of Consumer Civil Rights posted in a prominent location in the clinic.

3. Site has safety accommodations available or has an alternative plan in place for making program services available to persons with physical disabilities.
    - 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 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 hardware are operable with a single effort without requiring ability to grasp hardware (latch or push-bars instead of doorknobs)
    - 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.):

      _____

      _____

Resources:

1. OCR Fact Sheet: Your Rights Under Section 504 of the Rehabilitation Act:
https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/504.pdf

2. Section 1557: Frequently Asked Questions: https://www.hhs.gov/sites/default/files/section-1557-final-rule-faqs.pdf

3. Section 1557: Ensuring Meaningful Access for Individuals with Limited English Proficiency: https://www.hhs.gov/sites/default/files/1557-fs-lep-508.pdf

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

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SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Physician coverage is available 24 hours a day, 7 days a week
Facility Site Review Source:	
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Agency//Organization Source:	
Agency/Organization URL	

Background

Current clinic office hours are posted within the office or readily available upon request. Site-specific information about physician office hour schedule(s), as well as after-hours, on-call, and back-up physician coverage is available for personnel and members 24 hours a day, 7 days a week (plan-specific). Staff is also aware of the office system for providing follow up care.

- Arrangement/schedule for after-hours, on-call, supervisory back-up physician coverage is available to site staff and members after-hours.
- Contact information for off-site physician(s) is available at all times during office hours.
- Routine, urgent, and after-hours emergency care instructions/telephone information is made available to patients.

Resources

1. Sample Clinic Office Hours Sign
2. On-Call Provider Schedule and Contact Numbers Template

OFFICE HOURS

CLINIC NAME OR PROVIDER NAME(S):

_____

ADDRESS:

_____

HOURS OF OPERATIONS

_____
(DAY – DAY: TIME – TIME)

_____
(DAY – DAY: TIME – TIME)

OFFICE PHONE NUMBER

_____

AFTER HOURS CARE

_____

FOR EMERGENCIES

911

On-Call Provider Schedule and Contact Numbers

MM/YYYY - ____/_______				
Day	**Scheduled MD On-Call**	**Contact Number**	**Alternate MD On-Call**	**Alternate Contact Number**
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
After Hours				
Day	**Scheduled MD On-Call**	**Contact Number**	**Alternate MD On-Call**	**Alternate Contact Number**
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
After Hours				
Day	**Scheduled MD On-Call**	**Contact Number**	**Alternate MD On-Call**	**Alternate Contact Number**
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
After Hours				
Day	**Scheduled MD On-Call**	**Contact Number**	**Alternate MD On-Call**	**Alternate Contact Number**
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
After Hours				

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Patient Confidentiality		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) 22 CCR §53855; 28 CCR §1300.67.1, §1300.80 Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 45 CFR Section 164.524 https://codes.findlaw.com/ca/welfare-and-institutions-code/wic-sect-14124-1.html		

Purpose:

To ensure confidentiality of personal medical information is protected according to state and federal guidelines.

Policy:

Privacy: Patients have the right to privacy for dressing/undressing, physical examination, and medical consultation. Practices are in place to safeguard patient privacy. Because dressing areas and examination room configurations vary greatly, reviewers will make site-specific determinations.

Confidentiality: Personnel follow site policy/procedures for maintaining confidentiality of individual patient information. Individual patient conditions or information is not discussed in front of other patients or visitors, displayed or left unattended in reception and/or patient flow areas (this includes unattended electronic devices, and patient registration sign-in sheets with more than one unique patient identifier).

Electronic Records: Electronic record-keeping system procedures have been established to ensure patient confidentiality, prevent unauthorized access, authenticate electronic signatures, and maintain upkeep of computer systems. Security protection includes an off-site backup storage system, an image mechanism with the ability to copy documents, a mechanism to ensure that recorded input is unalterable, and file recovery procedures. Confidentiality protection may also include use of encryption, detailed user access controls, transaction logs, and blinded files.

Record Release: Medical records are not released without written, signed consent from the patient or patient's representative, identifying the specific medical information to be released. The release terms, such as to whom records are released and for what

purposes, and the expiration date of the consent to medical record release should also be described. This does not prevent release of statistical or summary data, or exchange of individual identifiable medical information between individuals or institutions providing care, fiscal intermediaries, research entities and State or local official agencies. (45 CFR Section 164.524)

Storage and Transmittal: Health care services rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, shall confidentially and securely keep and maintain records of each service rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, the beneficiary or person to whom rendered, the date the service was rendered, and any additional information as the department may by regulation require. FAX cover sheet shall have confidentiality statement.

Record Retention: Records required to be kept and maintained under this section (including minors under 18 years old) shall be retained by the provider for a period of 10 years from the final date of the contract period between the plan and the provider, from the date of completion of any audit, or from the date the service was rendered, whichever is later in accordance with 42 CFR 438.3(u) (WIC 14124.1).

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

DEPARTMENT OF Managed Health Care

Timely Access to Care

In California, health care consumers have the right to an appointment when needed.

The law requires health plans licensed by the DMHC to make primary care providers and hospitals available within specific geographic and time-elapsed standards. Health plans must ensure their network of providers, including doctors, can provide enrollees with an appointment within a specific number of days or hours.

Urgent Care

prior authorization **not required** by health plan
2 days

prior authorization **required** by health plan
4 days

Non-Urgent Care

Doctor Appointment

PRIMARY CARE PHYSICIAN
10 business days

SPECIALTY CARE PHYSICIAN
15 business days

Mental Health Appointment
(non-physician[1])
10 business days

Appointment
(ancillary provider[2])
15 business days

[1] Examples of non-physician mental health providers include counseling professionals, substance abuse professionals and qualified autism service providers.

[2] Examples of non-urgent appointment for ancillary services include lab work or diagnostic testing, such as mammogram or MRI, and treatment of an illness or injury such as physical therapy.

Timely Access to Care Requirements

DISTANCE
Provide access to a primary care provider or a hospital within 15 miles or 30 minutes from where enrollees live or work.

AVAILABILITY
Your health plan should have telephone services available on a 24/7 basis.

INTERPRETER
Interpreter services must be coordinated with scheduled appointments for health care services to ensure interpreter services are provided at the time of the appointment.

Unable to get an Appointment Within the Timely Access Standard?

If you are not able to get an appointment within the timely access standard, you should first contact your health plan for assistance at the toll-free number listed on your health plan card.

The DMHC Help Center is available at 1-888-466-2219 or www.HealthHelp.ca.gov to assist you if your health plan does not resolve the issue. The DMHC Help Center will work with you and your health plan to ensure you receive timely access to care.

If you believe you are experiencing a medical emergency, dial 9-1-1 or go to the nearest hospital. If your health issue is urgent, but not an emergency, and does not require prior approval or authorization from your health plan, you have the right to get care within 48 hours.

The waiting time for an appointment may be extended if a qualified health care provider has determined and made record that a longer waiting time will not be harmful to the enrollee's health.

DEPARTMENT OF Managed HealthCare

Acceso oportuno a la atención de salud

En California, los consumidores de atención de salud tienen derecho a recibir una cita cuando sea necesario.

La ley requiere que los planes de salud autorizados por el DMHC hagan que los proveedores de atención primaria y los hospitales estén disponibles dentro de normas específicas geográficas y de tiempo transcurrido. Los planes de salud deben garantizar que su red de proveedores, incluyendo los médicos, puedan proporcionar a los miembros una cita dentro de un número específico de días o horas.

Atención de urgencia

autorización previa **no requerida** por el plan de salud
2 dias

autorización previa **requerida** por el plan de salud
4 dias

Atención no urgente

Cita con el médico

MÉDICO DE ATENCIÓN PRIMARIA
10 días hábiles

MÉDICO ESPECIALISTA
15 días hábiles

Cita para servicios de salud mental
(proveedor que no es médico[1])
10 días hábiles

Cita
(proveedor auxiliar[2])
15 días hábiles

[1] Los ejemplos de proveedores de salud mental que no son médicos incluyen consejeros profesionales, profesionales para el tratamiento del abuso de sustancias y proveedores calificados de servicios para el autismo.

[2] Algunos ejemplos de citas no urgentes para servicios auxiliares incluyen análisis de laboratorio o pruebas de diagnóstico, como mamografías o resonancias magnéticas, y el tratamiento de una enfermedad o lesión, como la fisioterapia.

Requisitos del acceso oportuno a la atención de salud

DISTANCIA

Proporcionar acceso a un proveedor de atención primaria o a un hospital dentro de un radio de 15 millas de distancia o 30 minutos desde donde viven o trabajan los miembros del plan.

DISPONIBILIDAD

Su plan de salud debe tener servicios telefónicos disponibles las 24 horas, los 7 días de la semana.

INTÉRPRETE

Los servicios de intérpretes deben coordinarse con las citas programadas para servicios de atención de salud para garantizar que se proporcionen los servicios de intérpretes al momento de la cita.

¿No puede obtener una cita durante el plazo de la norma de acceso oportuno?

Si no puede obtener una cita dentro del plazo de la norma de acceso oportuno, primero debe comunicarse con su plan de salud para solicitar ayuda, llamando al número gratuito que aparece en su tarjeta del plan de salud.

El Centro de Ayuda del DMHC (Department of Managed HealthCare) está disponible llamando al 1-888-466-2219 o visite www.HealthHelp.ca.gov para ayudarle si su plan de salud no resuelve su problema. El Centro de Ayuda del DMHC trabajará con usted y su plan de salud para garantizar que tenga un acceso oportuno la atención de salud.

Si cree que está experimentando una emergencia médica, marque al 9-1-1 o vaya al hospital más cercano. Si su problema de salud es urgente, pero no es una emergencia, y no requiere aprobación o autorización previa de su plan de salud, usted tiene derecho a recibir atención en un plazo de 48 horas.

El tiempo de espera para una cita puede extenderse si un proveedor de atención de salud calificado ha determinado y registrado que un tiempo de espera más largo no será perjudicial para la salud del miembro.

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Management of Medical Advice Telephone Calls		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL MCPB letter 92-15 & Title 16, 1366b		

Purpose

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.

Definition

Triage: Medical screening of patients to determine their relative priority for treatment order.

Policy

In addition to the physician, only appropriately licensed medical personnel such as a CNM, NP, RN, or PA handles emergency, urgent, and medical advice/triage telephone calls. 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 discussion regarding the condition to the member, or to determine when a member needs to be seen by a licensed medical profession. Unlicensed personnel, such as medical assistants, may provide patient information or instructions only as authorized by the physician.

Note: Telephone triage is the system for managing telephone callers during and after office hours

Procedure:

The PCP will ensure that appropriate personnel handle emergent, urgent and medical advice telephone calls. This includes licensed medical personnel such as a CNM, NP, RN or PA. LVN's cannot perform triage independently. LVNs and unlicensed personnel such as medical assistants may provide patient information or instructions only as authorized by the physician

See also: PP_FSR-A_III C_Protocol for Appointment Triage and Timeliness

First Name Last Name – Title	Date
First Name Last Name – Title	Date

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Telephone Protocol when Staff Not Available & Monitoring After Hours System of How Clinic is Reached		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) 22 CCR §53855; 28 CCR §1300.67.1, §1300.80 Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Physician coverage is available and accessible 24 hours a day, 7 days a week. Effective clinic office management supports the provision of appropriate, coordinated health care services during and after office hours.

Policy:

Telephone answering machine, voice mail system or answering service is used whenever office staff does not directly answer phone calls.

Staff ensures that the telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated.

If your office has an after hour answering service, ensure that their staff members can speak languages other than English or ensure that they know how to connect to an interpreter over the telephone.

Procedure:

1. Call answered by a live voice (e.g. answering service or centralized triage):
    - If the caller believes the situation is an emergency, advice the caller to call 911 immediately, (or)
    - Proceed to the nearest Emergency Room or Urgent Care Center. Give the address of the emergency room or urgent care.

    - If the member indicates a need to speak with a physician, facilitate the contact with the

Physician by:

- Putting the caller on hold momentarily and then connecting the caller the on-call Physician, (or)
- Get the member's number and advise a physician will call them back within 30 minutes, (or)
- Giving the caller the pager number for the on-call physician and advising them to call back if they have not heard from the physician within 30 minutes.

Note: If a member indicates a need for interpreter services, facilitate the contact by accessing interpreter services.

2. Call answered by an answering machine:
    - If this is an emergency, please hang up and call 911 immediately. Hello, you have reached (Name of the Doctor/Medical Group). If you wish to speak with the physician on-call
    - Please hold and you will be connected to _____.
    - You may reach the on-call doctor directly by calling_____.
    - Please leave a message. The doctor will be paged, and you may expect a return call within 30 minutes
        - If you do not hear from the doctor within 30 minutes, please go to the Urgent Care Center, or the nearest Emergency Room, if an Urgent Care Center is not available.
    - Our urgent Care Center is located at _____.
        - [Appropriate language options should be provided for the location.]
3. Answering Machines/Answering Services/Centralized triage will be reviewed for accuracy and quality weekly, as well as, updated with any clinic hours, provider contact numbers and/or scheduling changes.

Please find Sample After Hours Script at the end of this sample policy.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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AFTER HOURS SAMPLE SCRIPT

One of the following scripts may be used by your medical group as a template for ensuring members have access to timely medical care after normal business hours.

I. CALLS ANSWERED BY A LIVE VOICE (E.G. ANSWERING SERVICE OR CENTRALIZED TRIAGE):

If the caller believes the situation is an emergency, advise the caller to call 911 immediately.

If the caller believes the situation is an emergency, advice the caller to call 911 immediately or proceed to the nearest Emergency Room or Urgent Care Center. Give the address of the Emergency Room or Urgent Care.

If the member indicates a need to speak with a physician, facilitate the contact with the physician by:

a) Putting the caller on hold momentarily and then connecting the caller the on-call physician, or

b) Get the members number and advise a physician will call them back within the hour, or

c) Giving the caller the pager number for the on-call physician and advising them to call back if they have not heard from the physician within one hour.

d) If a member indicates a need for interpreter services, facilitate the contact by accessing interpreter services.

II. CALLS ANSWERED BY AN ANSWERING MACHINE

If this is an emergency, please hang up and call 911immedicatly.

Hello, you have reached (Name of the Doctor/Medical Group). If you wish to speak with the physician on-call,

a) Please hold and you will be connected to (Provider Name) _____.

b) You may reach the on-call doctor directly by calling _____.

c) Please call _____. The doctor will be paged, and you may expect a return call within one hour. If you do not hear from the doctor within one hour, please go to the Urgent Care Center or the nearest Emergency Room if an Urgent Care Center is not available.

d) Our urgent Care Center is located at _____.

[Appropriate language options should be provided for the location.]

IMPORTANT: Effective telephone service after normal business hours providers for callers to reach a live voice or answering machine within 45 seconds.

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Protocol to Ensure Health Care Services are Readily Available		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

To maintain an organized system that is clear (in use) for scheduling appointments appropriately, notifying and reminding members of scheduled appointments, and following up of missed or canceled appointments.

To ensure appointments are schedule according to patient's clinical needs. Providing timely access to appointments for routine care, urgent care, prenatal care, pediatric periodic health assessments/immunization, adult initial health assessment, specialty care, and emergency care. Also, to give patients the opportunity to reschedule canceled and missed appointments. Missed appointments are an avoidable cost and resource inefficiency which impact upon the health of the patient and treatment outcomes.

Definition:

Triage: Medical screening of patients to determine their relative priority for treatment order.

Timeliness: The fact or quality of being done or occurring at a favorable or useful time.

Policy:

Medi-Cal Managed Care Health Plans require the following timeliness standards for access to appointments:

- Urgent Care: 48 hours
- Access to the first Prenatal Visit: 10 business days
- Non-urgent (Routine) Care: 10 business days

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.

Staff/ Automated system shall notify and remind members of scheduled and/or preventive screening appointments. Staff will also follow up on missed and/or canceled appointments via phone, text, mail, or email. At least two attempts to reach the patient will be made and documented in the patient's record.

Procedure for timely appointments:

The PCP will ensure that appropriate personnel handle phone triage to ensure appointments are schedule according to patient's clinical needs.

Follow these steps when receiving a call:

- 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.
- Question the member according to the PCP's or PPG's established instructions (who, what, when, and where) to assess the nature and extent of the problem.
- Schedule an appointment for the patient following Medi-Cal timeliness standards.

Procedure for notification of up-coming appointments:

Notification of up-coming scheduled routine/preventive appointment: Choose appropriate option for clinic.

- Option 1: Staff will call to remind patients of their schedule routine, preventive appointments _____day(s), hours prior to appointment.
- Option 2: The automated system _____ will phone/text/email to reminder patients of their scheduled routine, preventive appointments _____day(s), hours prior to appointment.

Procedure for verifying follow-up on missed and cancelled appointments:

For missed of cancelled appointments, staff or automated system will make two outreach attempts by _____(phone/text/email/mail) and outreach attempts will be documented in the patient's medical record.

Link:

DMHC **https://www.dmhc.ca.gov/Portals/0/Docs/DO/TAC_accessible.pdf**

The DMHC Help Center is available at 1-888-466-2219 or www.HealthHelp.ca.gov to assist you if your health plan does not resolve the issue. The DMHC Help Center will work with you and your health plan to ensure you receive timely access to care.

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

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Make Referrals Easy — Tool 21

Overview

Primary care practices refer patients to specialists, ancillary health care clinicians, labs and screening facilities, and elsewhere. Making the referral process easy for patients increases the chances that they will follow through, and that both you and the referral destination get all the information you need.

Actions

Refer patients to clinicians who coordinate care with you.

- Identifying, developing, and maintaining relationships with clinicians to whom you refer patients can make the referral process run smoothly.
- **Try to establish formal referral agreements** with key specialist groups and other clinicians.
- Don't continue to refer patients to clinicians who do not send information back to you, don't provide timely appointments for your patients, or otherwise fail to coordinate care.

Referral Agreements

Referral agreements spell out mutual expectations and responsibilities, such as:

- Which patients are appropriate to refer
- What information is needed before and after a referral
- Roles for both parties after the referral
- Setting aside appointments for urgent care

Don't rely on patients to relay information.

- **Share important information directly with the other office**, such as the reason for the referral, pertinent medical history, and test results.
- **Explore making electronic referrals.** Check whether your EHR has the capability to make referrals directly to other clinicians. If not, self-standing referral management systems are commercially available for purchase.
- Provide a detailed referral to the other clinician that contains all the information needed. The Improving Chronic Illness Site has a guide on Reducing Care Fragmentation, which includes a checklist of information to provide to specialists for each referral.
- **Get information sent directly back to you.** Make sure you get a full report back before your patient's next visit.

Consider language barriers.

- When making referrals for patients with limited English proficiency, **identify clinicians who are language concordant or have interpreter services**. See Tool 9: Address Language Differences for more information on language assistance.
- **Include information on your patient's language assistance needs** when making the referral.

Make sure the patient understands the reason for the referral.

- **Explain why** the patient needs to be seen by someone else, and what might happen if he or she is not seen.
- In the case of tests, **explain how you and the patient will use the information** to diagnose, manage, or decide on treatments for health conditions.
- In the case of screenings, **give a clear explanation of the risks and benefits.** Ultimately, it's up to the patient as to whether or not to undergo any particular test or screening.
- **Use the teach-back method** (see Tool 5: Use the Teach-Back Method) to confirm patient understanding.
- **Ask about and address any concerns or fears**.

Offer help with the referral.

- Ask patients if they would like your office to make the initial phone call.
- If staff members are making appointments for patients, make sure they first find out when the patients are available.
- Ask patients about transportation and other barriers to their completing the referral. Discuss how they could overcome these barriers. Use Tool 18: Link Patients to Non-medical Support to refer them to other services that could support their completion of the referral.

Provide clear instructions.

- For some referrals, patients will need to prepare in advance (e.g., fast, discontinue a medicine). Provide easy-to-understand instructions verbally and in writing.
- Explain the referral process fully (e.g., how you and the other clinician will exchange information, when the patient should return to your office).
- Give clear oral and written directions to get to the referral location.
- Use the teach-back method (see Tool 5) to confirm patient understanding.

Follow up on referrals.

- Confirm and document that the patient successfully completed the referral.
- Obtain information on the result of the referral and document in the medical record.
- Make sure the patient receives the results of any tests or screenings, even normal results.
- Provide patients positive feedback for completing referrals. Let patients see how you use the information obtained from tests or specialist visits.

- If the patient has not completed the referral, reinforce that you feel the patient could benefit, and review barriers.
- Determine whether the patient needs additional referrals.
- Get feedback from patients on the quality of the care provided. Stop making referrals to places that consistently receive negative reports.

Track Your Progress

Select a sample of referrals made during a week. Examine the referral records to calculate the percentage of referrals that included all relevant information. One month later, calculate the percentage of patients whose referral results are in their medical records.

Select a sample of patients who were sent for lab tests during a week. One month later, calculate the percentage of patients who have completed the test and the percentage who have been notified of the test results.

One month after implementing this Tool, ask a sample of patients who have not completed referrals why they did not follow through. Develop and implement an improvement plan to address the reasons they give. Repeat in 2, 6, and 12 months.

Resources

Care Coordination: Relationships and Agreements describes a package of changes, activities, and resources for primary care practices seeking to improve coordination.

Improving Your Office Testing Process: A Toolkit for Rapid-Cycle Patient Safety and Quality Improvement contains tools for referring to patients and following up on tests.

Referral Log

Date Referral sent to IPA	Patient Name and/or Medical Record Number	Referred to: Specialist/ Facility	Auth. Status & Date Approved/ Denied/ Deferred	Date Patient notified	Date of Appt / Services	DATE REPORT RECEIVED AND/OR COMMENTS

*Acuity of Referral: Emergent, Urgent or Routine

Referral Log

Date Referral sent to IPA	Patient Name and/or Medical Record Number	Referred to: Specialist/ Facility	Auth. Status & Date Approved/ Denied/ Deferred	Date Patient notified	Date of Appt / Services	DATE REPORT RECEIVED AND/OR COMMENTS

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Date Referral sent to IPA	Patient Name and/or Medical Record Number	Referred to: Specialist/ Facility	Auth. Status & Date Approved/ Denied/ Deferred	Date Patient notified	Date of Appt / Services	DATE REPORT RECEIVED AND/OR COMMENTS

*Acuity of Referral: Emergent, Urgent or Routine

Sample Referral Log

Referral Date	Patient's Name	D.O.B.	Provider Referred To	Specialty	Date of Appt	Date Consult Recv'd	7 Day Follow-up	30 Day Follow-up

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Policy and Procedure

Policy Name:	Referrals, Consults, and Diagnostic Studies		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

There is evidence of practitioner review of referrals, consults, and diagnostic tests.

Definitions:

Consultation: A consultation is a request from one physician to another for an advisory opinion. The consultant performs the requested service and makes written recommendations regarding diagnosis and treatment to the requesting physician. The requesting physician utilizes the consultant's opinion combined with his own professional judgment and other considerations (e.g. patient preferences, other consultations, family concerns, and comorbidities) to provide treatment for the patient. (https://aafp.org)

Referral: A referral is a request from one physician to another to assume responsibility for management of one or more of a patient's specified problems. This may be for a specified period of time, until the problem(s) is resolved, or on an ongoing basis. This represents a temporary or partial transfer of care to another physician for a particular condition. It is the responsibility of the physician accepting the referral to maintain appropriate and timely communication with the referring physician and to seek approval from the referring physician for treating or referring the patient for any other condition that is not part of the original referral.(https://aafp.org)

Policy and Procedure:

A. It is the policy of _____ to ensure a collaborative approach to care through the coordination of care, treatment and community-based services based on the patient's needs. This policy applies to all internal and external referrals. This includes but is not limited to specialty care, ancillary services, dental, mental health and substance abuse, self-management support, health education, and health promotion.
B. Electronically maintained medical reports must also show evidence of practitioner review, and may differ from site to site.

C. Evidence of practitioner review on any page of the report(s) or diagnostic result(s) that have multiple pages is acceptable.
D. There is evidence of practitioner review of consult/referral reports and diagnostic test results.
    a. There is documented evidence of practitioner review of records such as diagnostic studies, lab tests, X-ray reports, consultation summaries, inpatient/discharge records, emergency and urgent care reports, and all abnormal and/or "STAT" reports.
    b. Evidence of review may include the practitioner's initials or signature on the report, notation in the progress notes, or other site-specific method of documenting practitioner review.
E. There is evidence of follow-up of specialty referrals made, and results/reports of diagnostic tests, when appropriate.
    a. Consultation reports and diagnostic test results are documented for ordered requests.
    b. Abnormal test results/diagnostic reports have explicit notation in the medical record or separate system, including attempts to contact the member/guardian, follow-up treatment, instructions, return office visits, referrals and/or other pertinent information.
    c. Missed/broken appointments for diagnostic procedures, lab tests, specialty appointments and/or other referrals are noted, and include attempts to contact the member/parent and results of follow-up actions.
    d. If diagnostic appointments or referrals are documented in a separate system from medical records, they must be readily accessible and meet the medical retention requirements.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

Referral Log

Date Referral sent to IPA	Patient Name and/or Medical Record Number	Referred to: Specialist/ Facility	Auth. Status & Date Approved/ Denied/ Deferred	Date Patient notified	Date of Appt / Services	DATE REPORT RECEIVED AND/OR COMMENTS

*Acuity of Referral: Emergent, Urgent or Routine

Abnormal Results Contact Attempt Record

Please note: All attempts to contact a patient must be recorded in the patient's individual medical record at the time of the contact. This is a legal safeguard. Practice staff **MUST NOT** give out test results to patients unless expressly advised to by the PCP.

Patient's Name				
DOB				
Patient's Physical Initials				
Urgency of consult				
Type of test, e.g. blood, pap				
Time, date, phone no. & staff initials of 1st phone call				
Time, date, phone no. & staff initials of 2nd phone call				
Time, date, phone no. & staff initials of 3rd phone call				
Date 1st letter sent				
Mail returned?				
Date 2nd letter sent				
Mail returned?				
Date Registered Mail Sent				
Post office confirmation received receipt				

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Policy and Procedure

Policy Name:	Drug Samples		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 75032 and 75033. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL CA B&P Code, 4051.3 42 CFR 482.13-CMS Manual System; 42 CFR Part 482.25 16 CCR, Chapter 2, Division 3, Section 1356.32 16 CCR, Chapter 2, Division 3, Section 1356.32		

Purpose:

To ensure the safe and effective distribution, control, storage, use and disposition of drugs including sample and over-the-counter (OTC) drugs.

Definition:

A prescription drug not intended to be sold, given by drug representatives in sub-prescription-sized amount to promote the drug's sales. The Medical Board of California interprets "all drugs" to also include both sample and over-the-counter drugs

Policy:

- All drugs (including sample and over the counter), medication supplies, hazardous substances and prescription pads are securely stored in a lockable space (room, closet, cabinet, drawer) within the office/clinic. (CA B&P Code, 4051.3)
- A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. (42 CFR 482.13-CMS Manual System; 42 CFR Part 482.25)
- Keys to the locked storage area are available only to staff authorized by the physician to have access. (16 CCR, Chapter 2, Division 3, Section 1356.32)

- During business hours, the lockable space may remain unlocked ONLY if there is no access to this area by unauthorized persons and authorized clinic personnel remain in the immediate area at all times. At all other times, all drugs (including sample and over the counter), medication supplies, prescription pads and hazardous substances must be securely locked.

Procedure:

- Maintain list of drug samples (see Appendix A)
- Store drug samples in secure area at all times
- Maintain proper temperature, light, humidity, conditions of sanitation, ventilation, and segregation.
    - Room temperature where drugs are stored does not exceed 30 º C
- Maintain product integrity
- Maintain compliance with all applicable packaging and labeling laws, regulations, standards, and patient education requirements. Pharmacists should be involved in the organization's efforts to secure safe and effective low-cost medication for low-income patients.

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

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Monthly Medicine Cabinet Inventory: _ _/20 _ _					
Medication	Staff Initials	Date Entered	Manufacturer	Lot#	Expiration Date

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

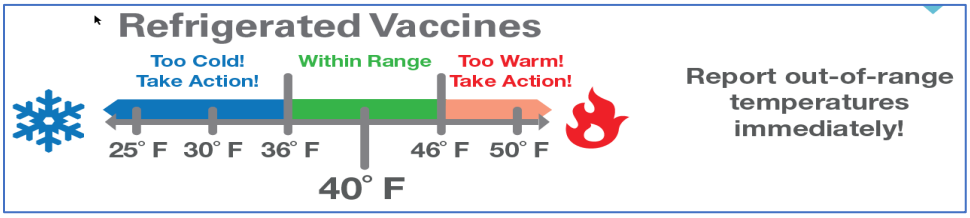
Subject:	Refrigerator Thermometer Temperature
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	Center for Disease Control and Prevention / Manufacturers
Agency//Organization Source:	Centers for Disease Control and Prevention
Agency/Organization URL	https://www.cdc.gov/vaccines/hcp/admin/storage/index.html

Background:

CDC recommends using purpose-built units designed to either refrigerate or freeze (can be compact, under the counter style or large units), stand-alone household units, and dedicated to storage of biologics.

Note: Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

Refrigerator temperatures are documented at least once a day (Best practice is twice daily). Site personnel must be able to verbalize the procedure used to promptly respond to OUT OF RANGE TEMPERATURES. Contacting VFC or manufacturer are acceptable procedures.



Vaccines are kept in a refrigerator maintained at 2-8ºC or 36-46ºF, and include, but are not limited to, DTaP, Td, Tdap, Hepatitis A, Hepatitis B, IPV, Pneumococcal, Rotavirus, Hib, Influenza (inactivated and FluMist), MCV, HPV, recombinant Zoster, or any combinations of these listed vaccines.

Purpose:

Proper vaccine storage and handling are important factors in preventing and eradicating many common vaccine preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised.

Resources: (See links or PDF copies in FSR Library)

CDC Vaccine Recommendation and Guidelines of the Advisory Committee on Immunization Practices
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html

CDC Vaccine Storage and Handling Toolkit
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Additional Information:

Use the following to determine the appropriate equipment size for your practice:

Choosing the right sized unit

Below are a few handy steps* for determining the ideal refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

Refrigerator:

Add the number of doses *on hand (current inventory)* from your last order form.

Public vaccine _____
Private vaccine +_____
Total doses =_____

Multiply (max inventory) x 1.25
Maximum doses =_____

2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine.

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000 – 2000	40 cu. ft
900 – 1000	36 cu. ft.
801 - 900	21 - 23 cu. ft
701 - 800	17 - 19.5 cu. ft.
400 – 700	11 - 16.7 cu. ft.
100 - 399	4.9 - 6.1 cu. ft.

3 Using this refrigerator and freezer guide as a reference, search for a storage unit that's properly sized and meets all VFC requirements. Whenever possible, choose biomedical-grade over household style units.

*Thanks to California's **eziz.org** for developing the original sizing guide above.

(Source: AAP Immunization Resources Storage and Handling Series Refrigerators, Freezers, and Vaccine Storage, https://www.aap.org/en-us/Documents/immunization_vaccinestoragerf.pdf)

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Resource Guide

Subject:	Freezer Thermometer Temperature
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	Vaccine Storage – Recommendations and Guidelines
Agency//Organization Source:	Centers for Disease Control and Prevention
Agency/Organization URL	https://www.cdc.gov/vaccines/hcp/admin/storage/index.html

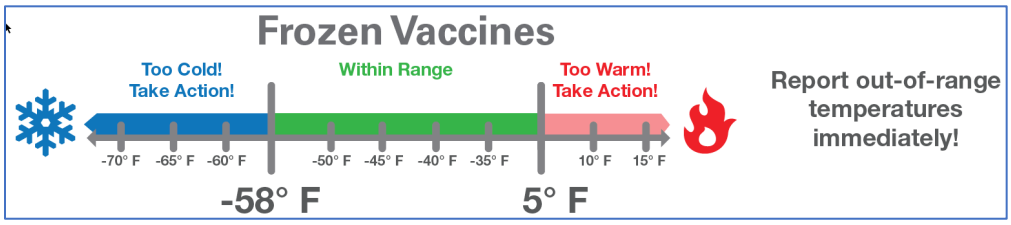
Background:

Varicella and MMRV vaccines are stored in the freezer at -15ºC or 5ºF, or lower, and are always protected from light.

- MMR may be stored in a refrigerator or freezer; VFC recommends MMR be stored in the freezer with MMRV.
- Never freeze vaccine diluents.

Please refer to "Power Malfunction and Vaccine Management" for concerns regarding procedures during power outages.

Notes:
Don't use dormitory-style refrigerator/freezer.
Don't use combo refrigerator/freezer unit.
Don't put food in freezer.
Don't store vaccines on shelves in freezer door



Purpose:

Proper vaccine storage and handling are important factors in preventing and eradicating many common vaccine preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised.

Procedure:

The characteristics of an appropriate **freezer storage system** includes:

- Maintain consistent temperatures between -58.0°F and 5.0ºF (between -50.0°C and -15.0ºC);
- Be either a stand-alone unit, or a pharmacy- or biologic-grade combination unit;

- Have sufficient capacity to store all the practice's frozen vaccines, along with sufficient frozen cold packs to stabilize temperatures, e.g. room to store Varivax, ProQuad and MMR II without crowding
- Defrost automatically (manual is acceptable if the office has access to an alternate storage unit when defrosting the freezer; the alternate storage unit must be able to maintain recommended temperatures and be monitored using a VFC-compliant data logger; temporary storage of vaccines in a cooler is unacceptable);
- Seal tightly and close properly;
- Be used only for vaccine storage.
- Certified data logging max/min displaying thermometer accurate to +/-0.5°C

Additional Information:

Freezers can be much smaller. Since only Varivax containing vaccine must be stored in it, a 1.5 cu ft unit can hold enough vaccine for 3 or 4 pediatricians. Generally it works best to have a second cold spare unit so units can be manually defrosted. If you have a cold spare and you get tight for room, the second unit, if set up with its own certified thermometer, can serve as an overflow unit as well. MMR can be stored frozen and most pediatricians store it in the freezer. Since only two visits (12m and 4y) require Varivax and MMR, the freezer can be placed in a less busy area of the office. Again, in selecting a size, base your needs on your current storage ability or visit another practice to see what works for them. (Source: AAP Immunization Resources Storage and Handling Series Refrigerators, Freezers, and Vaccine Storage, https://www.aap.org/en-us/Documents/immunization_vaccinestoragerf.pdf)

Choosing the right sized unit

Below are a few handy steps* for determining the ideal refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

Refrigerator:	
Add the number of doses *on hand (current inventory)* from your last order form.	
Public vaccine	_____
Private vaccine	+_____
Total doses	=_____
Multiply (max inventory)	x 1.25
Maximum doses	=_____

2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine.

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000 – 2000	40 cu. ft
900 – 1000	36 cu. ft.
801 - 900	21 - 23 cu. ft
701 - 800	17 - 19.5 cu. ft.
400 – 700	11 - 16.7 cu. ft.
100 - 399	4.9 - 6.1 cu. ft.

3 Using this refrigerator and freezer guide as a reference, search for a storage unit that's properly sized and meets all VFC requirements. Whenever possible, choose biomedical-grade over household style units.

*Thanks to California's **eziz.org** for developing the original sizing guide above.

Resources:

Storage Best Practices for Frozen Vaccines – Fahrenheit (F)
https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/storage-frozen.pdf
Vaccine Storage and HandlingToolkit
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

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Resource Guide

Subject:	Refrigerator and Freezer Thermometer Temperature Logs
Facility Site Review Source:	DHCS (Department of Health Care Services) / CDC (Centers for Disease Control and Prevention) & Immunization Action Coalition Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	See manufacturers recommendations and CDC recommendations and guidelines
Agency//Organization Source:	Centers for Disease Control and Prevention
Agency/Organization URL	https://www.cdc.gov/vaccines/hcp/admin/storage/index.html

Background:

Refrigerator and freezer temperatures must be checked at least once a day and documented (U.S. Pharmacopeia Convention Regulations and Recommendations). However, the CA DHCS Immunization Branch recommends checking temperatures twice a day, first thing in the morning and last thing at night.

Purpose:

Proper vaccine storage and handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases. Vaccine quality is the shared responsibility of everyone, from the time vaccine is manufactured until it is administered.

Links:

Refrigerator Log in Fahrenheit: https://www.immunize.org/catg.d/p3037f.pdf

Freezer Log in Fahrenheit: https://www.immunize.org/catg.d/p3038f.pdf

Refrigerator Log in Celsius: https://www.immunize.org/catg.d/p3037c.pdf

Freezer Log in Celsius: https://www.immunize.org/catg.d/p3038c.pdf

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Policy and Procedure

Policy Name:	Proper Maintenance, Storage of Drugs and Distribution of Controlled Substances		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL CA B&P Code, §4172, &16 CCR, Chapter 2, Division 13, Section 1356.3). Title22, Section 75037(d), CA Health and Safety Code, Sections 11053-11058 BPC 4172 16 CCR 1356.3 22 CCR 75032 and 75033 BPC 4051.3 16 CCR 1356.32 21 CFR 1301.75 21 CFR 1301.72		

Purpose:
Drugs are stored and dispensed according to State and Federal drug distribution laws and regulations. Drugs and medication supplies are maintained secured to prevent unauthorized access.

Definition:
Controlled substances are generally a drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a Controlled Drug.

Centrally acting drugs (such as narcotics, stimulants, and certain sedatives) are divided into five classes called schedules I through V.

The Comprehensive Drug Abuse Prevention and Control Act: Law enacted in 1970 to control the distribution and use of all depressant and stimulant drugs and other drugs of abuse or potential abuse as may be designated by the Drug Enforcement Administration (DEA) of the Department of Justice. See DEA website for Drug Schedules – www.dea.gov or write link to access, https://www.dea.gov/drug-scheduling

Policy:
The site will maintain competent, efficient, and ethical Pharmaceutical Services According to State and Federal statues for the health and safety of its patients.

Procedure:

1. Medications are kept separate from food, lab specimens, cleaning supplies, and other items that may potentially cause contamination. 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

2. Security: The Medical Board of California interprets "all drugs" to also include both sample and over-the-counter drugs. The Medical Board defines "area that is secure" to mean a locked storage area within a physician's office
    a. All drugs (including sample and over the counter), medication supplies, hazardous substances and prescription pads are securely stored in a lockable space (room, closet, cabinet, drawer) within the office/clinic. (CA B&P Code, 4051.3)
    b. A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. (42 CFR 482.13-CMS Manual System; 42 CFR Part 482.25)
    c. Keys to the locked storage area are available only to staff authorized by the physician to have access. (16 CCR, Chapter 2, Division 3, Section 1356.32)
    d. 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 drugs (including sample and over the counter), medication supplies, prescription pads and hazardous substances must be securely locked.

3. Drugs are handled safely and stores appropriately.

4. Preparation

    a. Drugs are prepared in a clean area, or "designated clean" area if prepare in a multipurpose room.

    b. 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, Section 351).

5. Storage:

    a. Drugs for external use are stored separately from drugs for internal use.

    b. 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, Section 211.142). Room temperature where drugs are stored does not exceed 30°C (86°F)

6. Controlled drugs are stored separately from other drugs, in a secured, lockable space accessible ONLY by authorized personnel (including physicians, dentists, podiatrists, physician assistants, licensed nurses and pharmacists) There is no need for the controlled substances to be double locked. **Controlled substances include all schedules I, II, III, IV and V substances.

    a. A dose-by-dose controlled substance distribution log is maintained (see Appendix A), including:
        i. Provider's DEA number
        ii. Name of medication
        iii. Original quantity of drug
        iv. Dose
        v. Date
        vi. Name of patient receiving drug
        vii. Name of authorized person dispensing drug and
        viii. Number of remaining doses

First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date

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Appendix A

Controlled Substances Distribution Log

Provider DEA #	Medication Name	Original Quantity of Drug	Dose	Date	Patient Receiving Drug	Authorized Person Dispensing Drug	Number of Remaining Doses

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	All stored and dispensed prescriptions drugs are appropriately labeled		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 22 CCR 75037(A) BPC 4170 and 4171		

Policy:

Each clinic that provides drug distribution services has written policies and procedures for the safe and effective distribution control, storage, use and disposition of drugs.

Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed.

Procedure:

Prescription Labeling:

- Labels shall be carefully preserved, and all medications shall be stored in their original containers.
- Each prescription medication dispensed is in a container that is not cracked, soiled, or without secure closures.
- Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed.
- Drug container is labeled with:
    - provider's name,
    - patient's name,
    - drug name,
    - dose, frequency,
    - route,
    - quantity dispensed, and
    - manufacturer's name and lot number.
- California Pharmacy Law does not prohibit furnishing a limited quantity of sample drugs if dispensed to the patient in the package provided by the manufacturer, no charge is made to the patient, and appropriate documentation is made in the patient's medical record.

Drug Distribution:

•Each clinic that provides drug distribution services has written policies and procedures for the safe and effective distribution control, storage, use and disposition of drugs.

•In order to prevent inadvertent exposure to out-of-range temperatures, vaccines should never be re-distributed beyond the manufacturer/distributer-to-clinic distribution chain unless during an emergency.
•In the event of necessary vaccine transport (emergency/power outage), vaccines must be packaged following CDC recommendations and include temperature monitoring devices during transport (approval is required for VFC providers prior to any vaccine transfer).

_____ _____

First Name Last Name – Title **Date**

_____ _____

First Name Last Name – Title **Date**

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Power Malfunction and Vaccine Management		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) https://www.fda.gov/vaccines-blood-biologics/vaccines/questions-about-vaccines Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Provide guidance for emergency vaccine maintenance and storage during power outage and/or malfunction.

Definition:

A power failure is when the electrical supply to a building or area is interrupted.

Policy:

Provide staff trainings and maintenance on the CDC Toolkit (see Link) on-site in an easily accessible area near the vaccine storage unit: Complete and review monthly - vaccine storage, handling, and transport. Site personnel must be able to verbalize the procedures in the plan used to promptly respond to OUT OF RANGE TEMPERATURES.

Procedure:

A. In the event that the building loses power for more than five minutes, the Office Lead and/or _____ shall check the circuit breaker.
B. If the power is restored by tripping the breaker, the Office Lead and/or _____shall record the time and date of the power outage, as well as any additional action that was needed in restoring power. Patient care should continue as scheduled unless otherwise informed by the Office Lead and/or _____.
C. If the power is not restored by tripping the breaker, the Office Lead and/or _____ shall notify all employees to continue patient care as regularly as possible. Patients shall be instructed to safely leave the building via the stairway, if able.
D. _____ (designated person) shall call PG&E (Pacific Gas and Electric) to determine the possible cause and length of the power outage.

a. In the event that PG&E is unaware of the power outage, the office doors should be locked and a sign requesting patients knock for assistance.

E. Quarantine vaccines until guidance is obtained.

F. Assess whether vaccine can be used after an emergency

G. Indicate the protocol for transporting vaccines to and from an alternative vaccine storage facility

H. The office maintains the following protocol:

a. Maintain contact information in checklist for general information

b. Maintain up-to-date contact information for:

i. Alternative vaccine storage (one or more)

ii. Transportation of vaccines

c. Keep a copy of emergency SOPs with emergency supplies and of multiple off-site locations such as homes of vaccine coordinator and alternate coordinator and with building manager, security staff and alternative storage facility

d. Maintain diagram to facility showing important elements, including doors, flashlights, packing materials, batteries, circuit breaker

b. Identify how to access your building and facility after hours

c. List vaccine storage unit specification (type, brand, model number, serial number)

d. List approved alternative vaccine storage facility (one or more)

e. Maintain and provide regular trainings for staff on vaccine protocols:

f. List and check packing supplies for vaccines and diluents for emergency transport

B. For VFC providers, follow program requirements for documentation and reporting.

Resources:

CDC Vaccine Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

CDC Impact of Power Outages on Vaccine Storage: https://www.cdc.gov/disasters/poweroutage/vaccinestorage.html

About the VFC Program: http://eziz.org/vfc/overview/

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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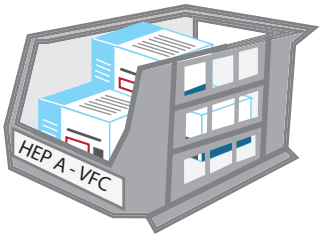
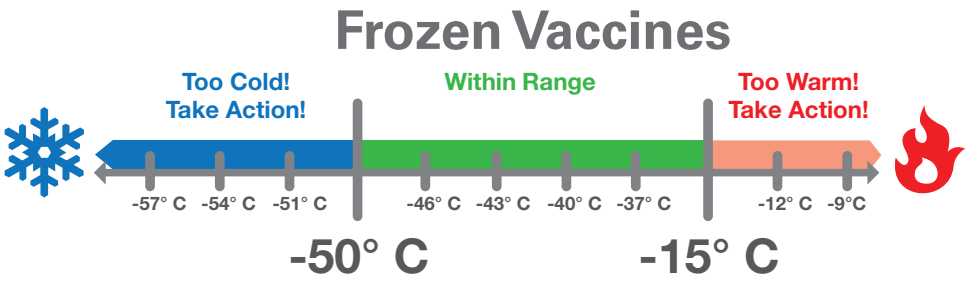
Storage Best Practices for Frozen Vaccines–Celsius (C)

1 Unpack vaccines immediately



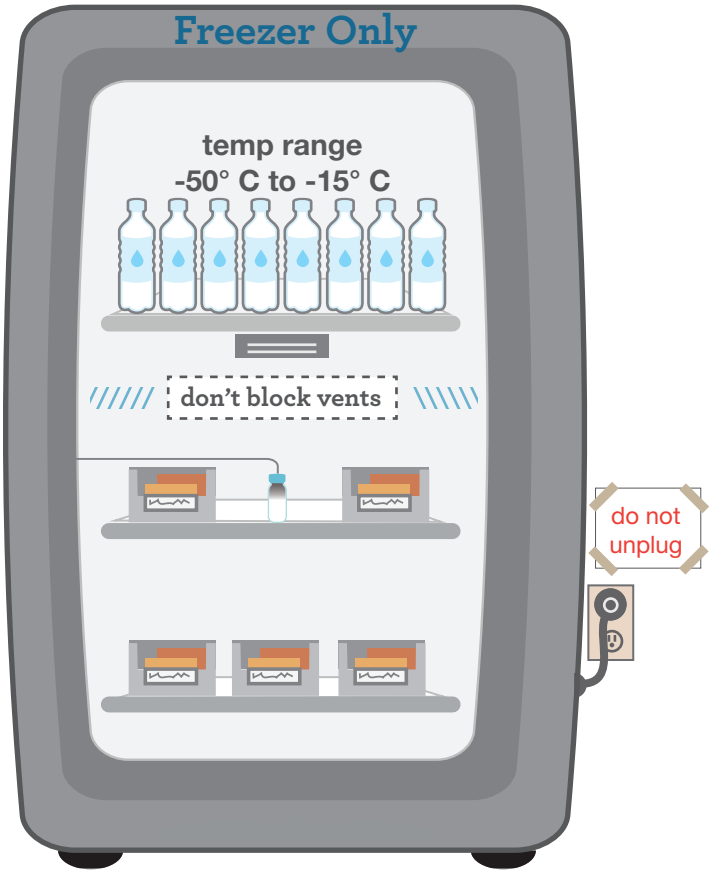
1. Place the vaccines in trays or uncovered containers for proper air flow.
2. Put vaccines that are first to expire in front.
3. Keep vaccines in original boxes with lids closed to prevent exposure to light.
4. Separate and label vaccines by type and public (VFC) or private.

2 Thermostat should be at the factory-set or midpoint temperature setting



Report out-of-range temperatures immediately!

3 Use vaccine storage best practices



DO

- Do make sure the freezer door is closed!
- Do use water bottles to help maintain consistent temperature.
- Do leave 2 to 3 inches between vaccine containers and freezer walls.
- Do post "Do Not Unplug" signs on freezer and by electrical outlet.

DON'T

- Don't use dormitory-style refrigerator/freezer.
- Don't use combo refrigerator/freezer unit.
- Don't put food in freezer.
- Don't store vaccines on shelves in freezer door.

CS243541-D Revision February 2018

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Centers for Disease Control and Prevention

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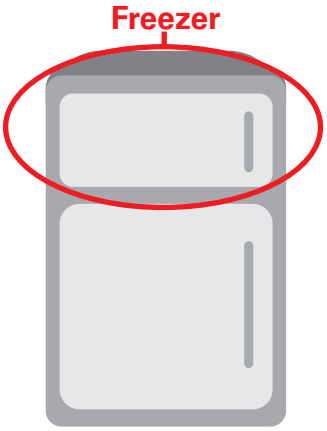
Visit www.cdc.gov/vaccines/SandH or contact your state health department for more information.

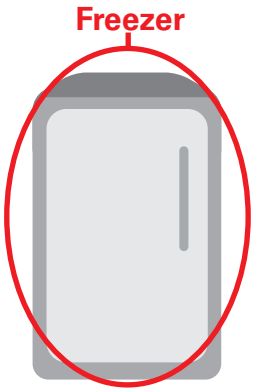
Test Your Knowledge

1 Which of the following units is the best for storing frozen vaccines?

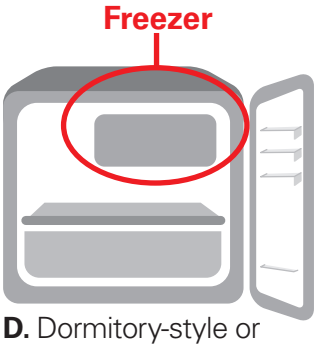
A. Full-size refrigerator/freezer (1 outside door/freezer is part of refrigerator)



B. Full-size refrigerator/freezer (2 outside doors, separate compartments)



C. Stand-alone freezer only unit



D. Dormitory-style or mini refrigerator (1 outside door/freezer is part of refrigerator)

2 Circle the TRUE statements:

A. It is okay to remove vaccines from the original boxes as long as they are stored in the freezer.

B. Water bottles in the freezer are important to help maintain consistent temperature.

C. You can "eye test" frozen vaccines—if they look frozen, they are okay.

D. Leave 2 to 3 inches between vaccine containers and freezer walls.

3 Circle the vaccines that MUST be stored in the freezer:

A. Varicella vaccine

B. MMR vaccine

C. Zoster vaccine live (ZVL)

D. Recombinant zoster vaccine (RZV)

4 One of the most common reasons that freezers are out of temperature range is:

A. Staff doesn't shut the freezer door

B. Power outage

C. The freezer thermostat is not working properly

D. The thermometer is broken

5 Frozen vaccines should be stored between _____° C and _____° C.

1. C—A stand-alone freezer is the best unit for storing frozen vaccines. NO vaccines—refrigerated or frozen—should ever be stored in a dormitory-style unit (D).

2. B and D are true statements. All vaccines should stay in their original boxes; proper temperature monitoring is very important and cannot be done by eye.

3. Varicella vaccine (A) and zoster vaccine live (ZVL) (C) MUST be stored in the freezer. MMR vaccine (B) can be stored in the refrigerator or freezer. Recombinant zoster vaccine (RZV) (D) MUST be stored in the refrigerator.

4. A—Believe it or not, staff not shutting the freezer door is one of the most common reasons a freezer is out of temperature range!

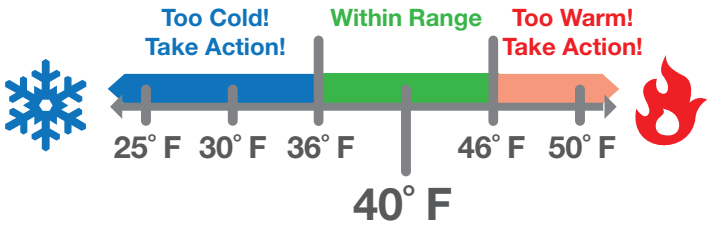
5. Frozen vaccines should be stored between -50° C and -15° C.

Temperature Monitoring Best Practices for Refrigerated Vaccines–Fahrenheit (F)

1 Store vaccines at ideal temperature: 40° F

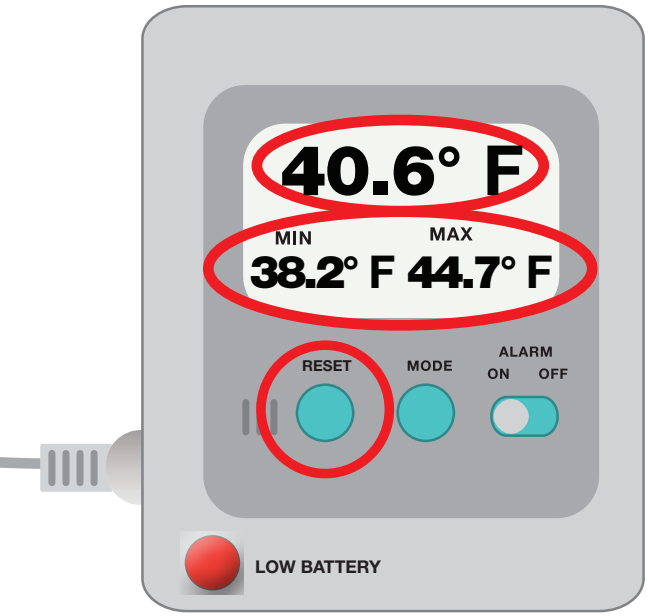
Never freeze refrigerated vaccines!
Exception: MMR can be stored in refrigerator or freezer

Refrigerated Vaccines



Report out-of-range temperatures immediately!

2 Record daily temperatures



3 steps, daily: Check and record min/max temperatures at the start of the workday.

1. **Min/Max:** The coldest and warmest temperatures in the refrigerator since you last reset the thermometer

   Note: If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday)

2. **Reset:** The button you push after you have recorded the min/max temperatures

3. **Current temperature:** Check current temperature each time you access vaccines in the refrigerator

3 Take action if out of range!

- Contact your state or local health department immediately. Or for private vaccines, call the manufacturer directly.
- Tell them the total amount of time the refrigerator temperature was out of range.

Best Practices

- **Take your time.** Check and record temperatures accurately.
- **Make your mark!** Initial the log when recording temperatures.
- **Leave it blank.** If min/max temperatures were not recorded, leave the space blank!

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Centers for Disease Control and Prevention

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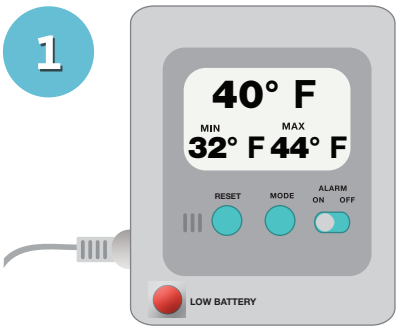
CS243541-A Revision February 2018

Visit **www.cdc.gov/vaccines/SandH** or contact your state health department for more information.

Test Your Knowledge

Review the temperature readings below and select the correct answer.

1



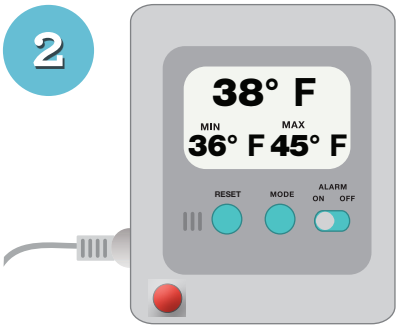
A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

2



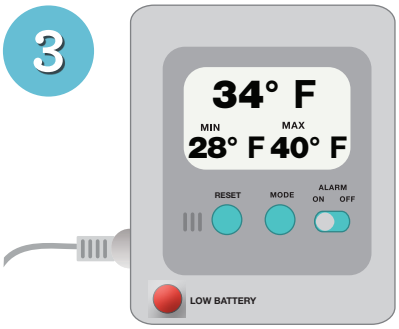
A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

3



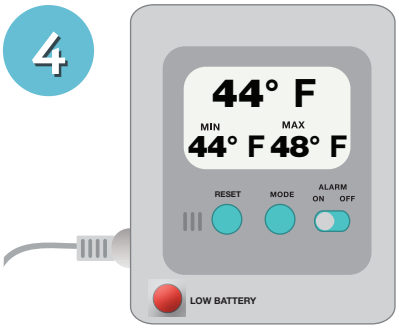
A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

4



A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

5

"Take action" means (circle any that apply):

A. Remove all vaccines that are out of range and discard them.

B. Call the state/local VFC program (or manufacturer for private vaccines) for guidance.

C. Notify the practice's vaccine coordinator to get the refrigerator temperature back in range.

D. Thaw any vaccines that were frozen for 45 minutes.

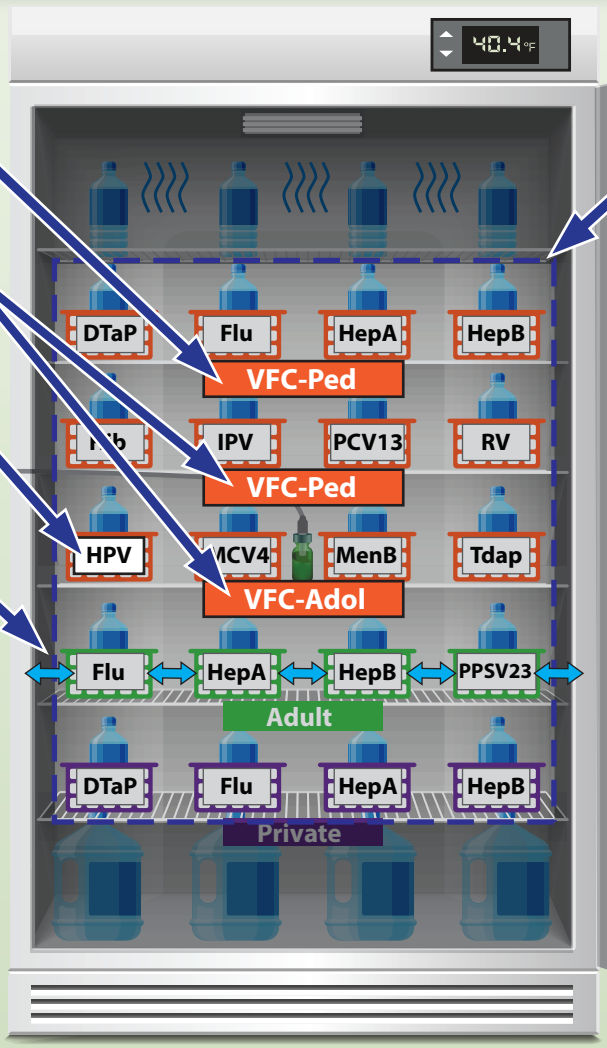
Answers: 1-B, 2-A, 3-D, 4-B, 5-B and C

Setting Up Vaccine Storage Units

Organize refrigerators and freezers to facilitate vaccine management and reduce administration errors. Do not store vaccines until storage units have stabilized within their OK ranges for 3-5 days. MMR, MMRV, and Varicella must be stored in the freezer. Plan to store all other VFC vaccines in the refrigerator.

Sample Refrigerator

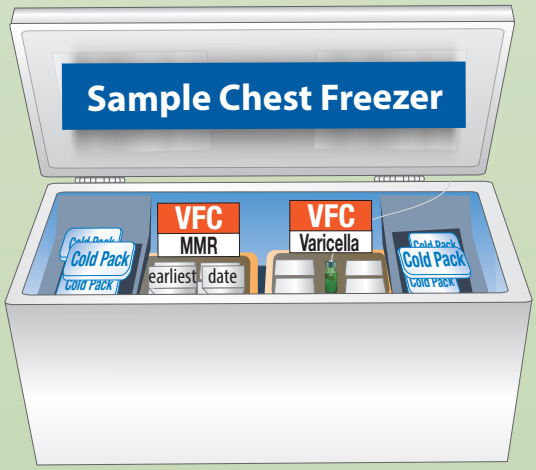
- ✓ Clearly label VFC and private vaccines.
- ✓ Group vaccines (pediatric, adolescent, adult).
- ✓ Label shelf space or baskets to make vaccines easy to find.
- ✓ Position vaccines or baskets 2-3 inches away from walls, floor, and other baskets.
- ✓ Store vaccines in original packaging with earliest expiration date in front.
- ✓ Diluents may be stored next to refrigerated vaccines unless manufacturer states otherwise. Never store diluents in the freezer.
- ✓ If necessary, medications or biologics may be stored below vaccines and on a different shelf.



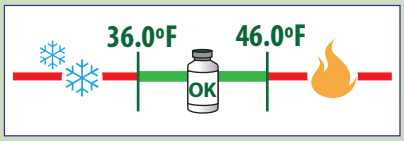
Usable space for vaccine is inside dashed lines.

- ✗ Do not block air vents.
- ✗ Do not stack baskets on top of each other.
- ✗ No vaccines in doors.
- ✗ No food or beverages.

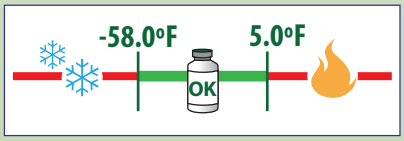
Sample Chest Freezer



Refrigerator temperatures



Freezer temperatures



VFC Field Rep:

www.eziz.org

Vaccine Storage and Handling Toolkit

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

January 2019

CS296544-B

Table of Contents

Disclaimer: This document provides best practices and Centers for Disease Control and Prevention (CDC) recommendations on storage, handling, and transport of vaccines and diluents. It also provides information on vaccine storage and handling requirements related to the Vaccines for Children program. Use of trade names and commercial sources in this toolkit is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or CDC.

Introduction

Proper vaccine storage and handling are important factors in preventing and eradicating many common vaccine-preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised.

This toolkit provides information, recommendations, and resources to assist you in properly storing and handling your vaccine supply. The Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit brings together best practices from the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization,* product information from vaccine manufacturers, and results of scientific studies. Implementing these best practices and recommendations will help protect your patients, safeguard your vaccine supply, and avoid the unnecessary costs of revaccinating patients and replacing expensive vaccines.

For specific, detailed storage and handling protocols for individual vaccines, always refer to the manufacturers' product information and package inserts,* or contact the manufacturer directly.

Vaccines for Children Program

The Vaccines for Children (VFC) program provides vaccines at no cost to eligible children. VFC providers are important partners in making sure VFC-eligible children receive viable, properly handled vaccine.

This toolkit provides general background information on many of the VFC storage and handling requirements and illustrates best practices essential to safeguarding the public vaccine supply.

If you are a VFC provider or receive other vaccines purchased with public funds, consult your state or local immunization program (referred to throughout this document as "immunization program"*) to ensure you are meeting all mandatory storage and handling requirements that are specific or tailored to your jurisdiction.

You may see vendors use terms such as "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC/VFC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

*ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html

Manufacturers' package inserts: www.immunize.org/packageinserts/

Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Introduction

How to Use the Vaccine Storage and Handling Toolkit

This toolkit outlines CDC recommendations for vaccine storage and handling.

This list shows the icons you will see throughout the toolkit and their meanings:

ICON	DESCRIPTION
	CDC Recommendation – CDC recommends this as a minimal action to protect your vaccine supply.
	CDC Best Practice – CDC recommends best practices as additional actions, practices, and procedures to enhance protection of your vaccine supply.

Additional CDC vaccine storage and handling information is available at:

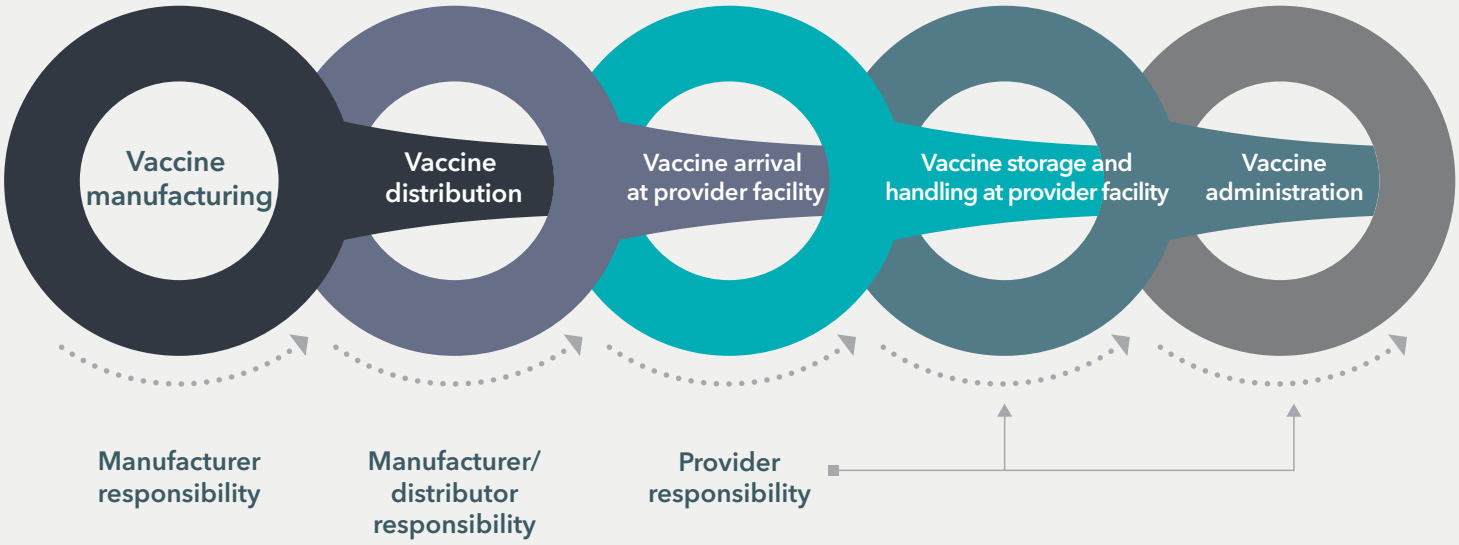
- Vaccine storage and handling home page:
  www.cdc.gov/vaccines/recs/storage/default.htm
  (sign up for notifications about updates)
- Educational webinars and continuing education for health care providers:
  www.cdc.gov/vaccines/ed/courses.html
- Contact information for state/local immunization programs:
  www.cdc.gov/vaccines/imz- managers/awardee-imz-websites.html
- E-mail specific questions to CDC: NIPInfo@cdc.gov

Proper vaccine storage and handling play critical roles in efforts to prevent vaccine-preventable diseases. Vaccines exposed to storage temperatures outside the recommended ranges may have reduced potency, creating limited protection and resulting in the revaccination of patients and thousands of dollars in wasted vaccine.

Proper storage and handling begin with an effective vaccine cold chain.

A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the patient.

Cold Chain Flowchart



If the cold chain is not properly maintained, vaccine potency may be lost, resulting in a useless vaccine supply.

Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

Exposure to any inappropriate conditions can affect potency of any refrigerated vaccine, but a single exposure to freezing temperatures (0° C [32° F] or colder) can actually destroy potency. Liquid vaccines containing an adjuvant can permanently lose potency when exposed to freezing temperatures.

When the cold chain fails

Assuring vaccine quality and maintaining the cold chain are shared responsibilities among manufacturers, distributors, public health staff, and health care providers.

An effective cold chain relies on three main elements:

- A well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

Results of a cold chain failure can be costly.[1,2,3] ACIP's *General Best Practice Guidelines for Immunization* states, "vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated."[4]

A break in the cold chain can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines.

More importantly, patients refusing revaccination can remain unprotected from serious, vaccine-preventable diseases.

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For example, inactivated vaccines—even when exposed to freezing temperatures—may not appear frozen, giving no indication of reduced or lost potency.

By following a few simple steps and implementing CDC-recommended storage and handling practices, providers can ensure patients receive high-quality vaccine that has not been compromised.

1. Department of Health and Human Services, Office of Inspector General. Vaccines for Children Program: Vulnerabilities in Vaccine Management, June 2012, oig.hhs.gov/oei/reports/oei-04-10-00430.asp.
2. Gazmararian JA, Oster NV, Green DC, Schuessler L, Howell K, et al. Vaccine storage practices in primary care physician offices: assessment and intervention. *Am J Prev Med* 2002;23(4):246–53.
3. Bell KN, Hogue CJR, Manning C, Kendal AP. Risk factors for improper vaccine storage and handling in private provider offices. *Pediatrics* 2001;107(6):1–5.
4. Centers for Disease Control and Prevention. ACIP's *General Best Practice Guidelines for Immunization*, https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Vaccine storage and handling practices are only as effective as the staff that implements them. Staff that is well-trained in general storage and handling principles and organization-specific storage and handling standard operating procedures (SOPs) is critical to ensuring vaccine supply potency and patient safety.

Staff Training

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and be familiar with your facility's storage and handling SOPs. If you are a VFC provider or have vaccines purchased with public funds, contact your immunization program* for specific state requirements related to training, policies, and procedures.

Online Training Resources

CDC's *You Call the Shots*: Vaccine Storage and Handling† is a free, online training module focused on storage and handling requirements.

Check with your immunization program* and professional organizations to see what vaccine storage and handling training resources they offer.

Storage and Handling SOPs

CDC recommends your facility develop and maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). SOPs will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs help ensure proper procedures are followed and problems are identified, reported, and corrected. SOPs should also provide guidance for emergencies such as equipment malfunctions, power failures, or natural disasters.

Storage and handling plans and SOPs should contain plans and information for three major areas (see the **Vaccine Storage and Handling SOP Worksheet**):

- General information—include contact information for vaccine manufacturers, equipment service providers, and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements
- Routine storage and handling SOPs—include information for all aspects of vaccine inventory management, from ordering to monitoring storage conditions
- Emergency vaccine storage, handling, and transport SOPs—outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions

Worksheets to assist you in developing your organization's routine and emergency SOPs are located in the resources section.

Train staff on routine vaccine storage and handling and emergency SOPs. Keep SOPs near vaccine storage units and make sure staff knows where to find them. Document all training completed with dates and participant names.

Storage and handling training should be completed:

- As part of new employee orientation
- Annually as a refresher for all staff involved in immunization and vaccine storage and handling activities
- Whenever new vaccines are added to inventory
- Whenever recommendations for storage and handling of vaccines are updated

*Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

†You Call the Shots: Vaccine Storage and Handling: www.cdc.gov/vaccines/ed/youcalltheshots.html

Vaccine Coordinator Recommendations

Designate a primary vaccine coordinator. This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on your facility's storage and handling SOPs.

Coordinator responsibilities should include:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures at start of each workday‡
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Organizing vaccine-related training and ensuring staff completion of training
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport (when necessary) per SOPs
- Overseeing emergency preparations per SOPs:
  - Tracking inclement weather conditions§
  - Ensuring appropriate handling of vaccines during a disaster or power outage‖

Coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. Ensure the coordinator has trained the delegate(s) and documented competency for the specific task(s) assigned.

Staff Training and SOP Best Practices

- Review and update SOPs annually.
- Appoint an alternate vaccine coordinator to act in the absence of the primary coordinator.
- The alternate coordinator, like the primary coordinator, should be an expert in routine and emergency SOPs.

‡This is a VFC provider requirement.

§The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness: www.fema.gov/.
The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/.

‖The National Oceanic and Atmospheric Administration (NOAA) provides up-to-date information on U.S. weather conditions:
www.weather.gov/
www.goes.noaa.gov/

SECTION THREE: Vaccine Storage and Temperature Monitoring Equipment

It is important your facility has proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed. This equipment protects patients from inadvertently receiving compromised vaccine and your facility against costs of revaccinating patients, replacing expensive vaccines, and losing patient confidence in your practice.

Vaccine Storage Units: Refrigerator and Freezer Recommendations

There are several types of vaccine storage units available. Purpose-built units are specifically designed to store vaccines. However, household-grade units are also an acceptable option for vaccine refrigeration under the right conditions.

- **Use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze**. These units can be compact, under-the-counter style or large.

Purpose-built units, sometimes referred to as "pharmaceutical-grade," are designed specifically for storage of biologics, including vaccines. These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor)
- Fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.

Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As the name implies, these units are primarily designed and marketed for home use. However, the freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate freezer unit is necessary.

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

Storage unit doors

A door that is not sealed properly or left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider using safeguards to ensure the doors of the unit remain closed—for example, self-closing door hinges, door alarms, or door locks.

Storage Unit Best Practices

To fully ensure the safety of vaccines, equipment should include a recommended unit with enough space to accommodate your maximum inventory without crowding.

Storage Unit Placement

Good air circulation around the outside of the storage unit is important. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

You may see vendors use terms such as "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC/VFC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

Stabilizing Temperatures in New and Repaired Units

It may take two to seven days to stabilize the temperature in a newly installed or repaired refrigerator and two to three days for a freezer.

Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday for two to seven days. If temperatures cannot be recorded digitally, check and record temperatures a minimum of two times each workday. Once you have two consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use.

Temperature Ranges

Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F).* Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

Consult the owner's manual for instructions on how to operate the thermostat. Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

Temperature Monitoring Device (TMD)

Every vaccine storage unit must have a TMD. An accurate temperature history that reflects actual vaccine temperatures is critical for protecting your vaccines. Investing in a reliable device is less expensive than replacing vaccines wasted due to the loss of potency that comes from storage at out-of-range temperatures.

- **CDC recommends a specific type of TMD called a "digital data logger" (DDL).** A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals.

Many DDLs use a buffered temperature probe, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe match vaccine temperatures more closely than those measured by standard thermometers, which tend to reflect only air temperature.

Temperature data from a DDL can either be downloaded to a computer using special software or retrieved from a website. The software or website may also allow you to set the frequency of temperature readings. Reviewing DDL data is critical for vaccine viability, so it is important to decide whether independent software or a website program works best for your facility.

- **Keep the data for three years so it can be analyzed for long-term trends and/or recurring problems.** Those receiving public vaccine may need to keep records longer as required by state regulations.

- **Use a DDL or other appropriate TMD for:**
  - Each vaccine storage unit
  - Each transport unit (emergency or non-emergency)

Have at least one backup TMD in case a primary device breaks or malfunctions.

- **Use DDLs with the following features:**
  - Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)†
  - Alarm for out-of-range temperatures
  - Low-battery indicator†

*Probes that are permanently embedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested.

†Since these devices are typically battery-operated, have a supply of extra batteries on hand.

- Current, minimum, and maximum temperature display‡
- Recommended uncertainty of +/-0 .5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

Use DDLs with a current and valid Certificate of Calibration Testing.

Certificate of Calibration Testing

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards.

A DDL's Certificate of Calibration Testing should include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/-0 .5° C (+/-1° F) or less

To determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Calibration testing should be done every one to two years or according to the manufacturer's suggested timeline. TMDs can experience a "drift" over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally-accepted standards.

Mishandling a TMD can affect its accuracy. If a TMD is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated TMD. If there is any question about accuracy, the device should be replaced or sent for calibration testing.

Monitoring Vaccine Temperature and Vaccine Equipment

Monitoring vaccine storage equipment and temperatures are daily responsibilities to ensure the viability of your vaccine supply and your patients. Implementing routine monitoring activities can help you identify temperature excursions quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Certain types of TMDs have significant limitations and should not be used to measure temperatures in a vaccine storage unit. These devices can be difficult to read and, because they only show the temperature at the exact time they are checked, may fail to detect temperatures outside the recommended range.

CDC does not recommend the following TMDs:

» Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial

» Bimetal stem TMDs

» TMDs used for food

» Chart recorders

» Infrared TMDs

» TMDs that do not have a current and valid Certificate of Calibration Testing

Please note: Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging vaccines.

‡Battery changes may affect temperature accuracy and may warrant checking against a known, calibrated TMD. Check with the device's manufacturer for specific information on battery changes.

Power Supply

Food and beverages should never be stored in the unit with vaccines.

Even with appropriate equipment and temperature monitoring practices in place, power disruption can result in destruction of the entire vaccine supply. Precautions should always be taken to protect the storage unit's power supply.

- **Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off.**
- **Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.**
- **Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.**
- **Label fuses and circuit breakers to alert people not to turn off power to a storage unit.**
- **Use caution when using power outlets that can be tripped or switched off and avoid using:**
  - Built-in circuit switches (may have reset buttons)
  - Outlets that can be activated by a wall switch
  - Multioutlet power strips

If built-in circuit switches or power strip surge protection must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer. Contact the unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, or surge protection.

If the entire storage unit is affected by a temperature excursion because of a power supply issue or unit malfunction, refer to your facility's emergency SOPs.

Organizing and Storing Vaccine

Correctly organizing and placing vaccines in a storage unit helps prevent conditions that could reduce vaccine potency or cause vaccine failure.

Temperature Monitoring

Regular checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines, and remove any expired vaccines. Check the temperature each time vaccines are accessed in the unit.

Review storage unit temperature readings and review continuous DDL software or website information weekly for changes in temperature trends that might require action.

If there appears to be any fluctuation in temperature, troubleshoot the problem based on additional information provided in this toolkit, manufacturer manuals, and/or your office storage and handling SOPs.

- **Store vaccines in their original packaging with lids closed until ready for administration.** Vials and manufacturer-filled syringes should always be stored in their original packaging. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency, and may be more difficult to track for expiration dates. They may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines. For certain purpose-built units, it is recommended that vaccine be stored outside of the packaging. If this is the case, follow the manufacturer's guidance for vaccine storage.
- **Check and record storage unit minimum and maximum temperatures at the start of each workday.**

  Record:

  - Minimum/maximum temperature
  - Date
  - Time
  - Name of person who checked and recorded the temperature
  - Any actions taken if a temperature excursion occurred
  - If a reading is missed, leave a blank entry in the log.

Temperature Excursions

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts* is considered a temperature excursion. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable.

CDC recommends the following steps in the event of a temperature excursion:

1. Any staff who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
2. Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a seperate container apart from other vaccines (do not discard these vaccines).

BEST PRACTICES

Organizing and Storing Vaccine

To confirm vaccines are stored correctly and to minimize the risk of administration errors, implement the following practices:

- Store each type of vaccine or diluent in its original packaging and in a separate container.
- Position vaccines and diluents two to three inches from the unit walls, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in deli, fruit, or vegetable drawers, or on refrigerator door shelves. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.
- Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves.
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store diluent in a freezer.
- Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
    - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines.
        - —Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
        - —The freezer of a household-grade unit may be used for non-vaccine, medical storage, so long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.
- Arrange vaccines and diluents in rows and allow space between them to promote air circulation.
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.

*Manufacturers' vaccine package inserts: www.immunize.org/fda/

BEST PRACTICES

Place water bottles on the top shelf and floor and in the door racks. Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.

Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

How to Store Vaccines

3. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem should begin to document the event with the following information[§]:
   a. Date and time of the temperature excursion
   b. Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
   c. Name of the person completing the report and description of the event[‖]:
      — General description of what happened
      — The length of time vaccine may have been affected, if using a DDL
      — Inventory of affected vaccines
      — List of items in the unit (including water bottles) other than vaccines
      — Any problems with the storage unit and/or affected vaccines before the event
      — Other relevant information
4. Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.
5. Contact your immunization program and/or vaccine manufacturer(s) per your SOPs for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination. Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.
6. Complete your documentation of the event, including:
   a. Action taken
      — What you did with vaccine and how long it took to take action
      — Whom you contacted and instructions received
      — What you did to prevent a similar future event
   b. Results
      — Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)
      — Other comments

[§]The Immunization Action Coalition has developed a Temperature Monitoring Log and a Vaccine Storage Troubleshooting Record to support these activities.

[‖]Responses from vaccine manufacturers to events depend on information given by the provider to the manufacturer. If different information about the same event is provided to the same manufacturer, this can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar.

Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices

Storage units and TMDs need regular maintenance to ensure proper operation.

Never allow vaccines to remain in a malfunctioning unit for an extended period of time. If you believe your your unit has failed, implement your emergency SOPs.

Conduct routine maintenance for all vaccine storage units and related equipment so that your equipment functions at maximum efficiency.

- Check seals and door hinges.
- Clean coils and other components per manufacturer direction.
- Defrost manual-defrost freezers.
- Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of a temperature excursion.
- Test any backup generator quarterly and have it serviced annually.

Troubleshooting Equipment Problems

Adjusting Storage Unit Temperatures

Storage unit temperatures may need to be adjusted over time. In some situations, thermostats may need to be reset in summer and winter, depending on room temperature.

Temperature adjustments should:

- Be made by the primary or alternate vaccine coordinator, based on information from the TMD and temperature monitoring log.
- Be done at a time that is not during a busy workday when the unit door is being frequently opened and closed.

Remember that temperatures within any storage unit will vary slightly, even with normal use. Therefore, before making any adjustment:

- Confirm the unit is securely plugged into a power source.
- Check the temperature inside the storage unit.
- Wait 30 minutes, without opening the door, to allow the temperature to stabilize and then check it again to determine if the thermostat should be adjusted.

If you believe there could be an issue with your TMD, use your backup device to confirm the temperature.

If you confirm that an adjustment is needed:

1. Refer to the owner's manual for detailed instructions.
2. Make a small adjustment toward a warmer or colder setting by turning the thermostat knob slowly to avoid going outside the correct temperature range.
3. Once the adjustment is made, allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
4. Recheck the temperature.
5. Repeat these steps as needed until the temperature has stabilized at around 5° C (40° F) for a refrigerator or between -50° C and -15° C (-58° F and +5° F) for a freezer.
6. Consider placing additional water bottles in the unit to help improve temperature stability.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at high risk. Use your SOPs to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

If you are using a combination storage unit, note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen vaccines in the refrigerator.

Repeated Alarm Alerts

If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause. Do basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your SOPs. A repair technician should check your equipment to determine the need for repair or replacement.

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, and ensures your facility has the vaccines your patients need. Vaccines are expensive, so making sure they are unpacked, stored, prepared, administered, and transported correctly is critical.

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents get too warm, they cannot be used. Be sure all staff knows that vaccine deliveries require immediate attention.

Vaccine Delivery

Scheduling and Receiving Deliveries

Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive. Vaccines must always be immediately checked and stored properly upon arrival.

Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit because the cool packs shipped with the vaccine may make the packaged vaccine too cold if placed inside the storage unit.

Immediately examine shipments for signs of damage and to guarantee receipt of the appropriate vaccine types and quantities.

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
  - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
- If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
- Immediately check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
- Immediately check the cold chain monitor (CCM), a device used to monitor vaccine temperatures during transport, if one was included, for any indication of a temperature excursion during transit.

Vaccine Inventory Accounting

Stock Counts

Stock records are used to determine the type and amount of vaccines your facility should stock to meet the needs of your patients. At least once a month and before placing any vaccine order, count all vaccine and diluent doses to make sure the number of doses in the storage unit matches the number of doses documented in the stock record. Always check expiration dates while counting stock and remove any expired doses immediately.

Stock Records

Use a stock record to account for and document every dose of vaccine. This record will help you keep track of your inventory and can be in either paper or electronic form. This record should be updated weekly and include the vaccine delivery information below:

- Date of delivery and initials of the person who unpacked the box
- Vaccine and diluent name and manufacturer
- Number and expiration date for each lot
- Number of doses received
- Condition of each vaccine and diluent upon arrival
- CCM reading if included in the shipping container
- Number of doses used
- Balance of remaining doses after subtracting the amount used

Note: State and local programs that have an immunization information system (IIS) with vaccine inventory accounting functions will require VFC providers to use the IIS to track their inventory.

Tally Sheets

Tally sheets can help keep stock records up to date. Place tally sheets outside the storage unit door (or another easily accessible location), and have staff use tick marks to keep a count of every dose removed from the unit.

If the numbers in the storage unit do not match the doses documented in the stock record, enter the correct number based on your count on a separate line below the old balance on your stock record. Make a note next to the new entry indicating that your count confirmed the new balance and sign it. Use the corrected balance for calculating stock quantities in the future.

If you receive multiple doses of the same vaccine in the same presentation from the same lot with the same expiration date, you can document these doses as one entry on the stock record. Indicate the total number of doses received, regardless of how many vials or syringes the doses came in. For example, if you receive 10 single-dose vials of the same vaccine with the same lot number and expiration date, you can make a single entry on the stock record, noting that 10 doses were received.

If there are discrepancies between the contents and the packing list or other concerns about the contents, immediately notify the vaccine manufacturer. If you are a VFC provider or receive vaccines purchased with public funds, contact your immunization program.*

Diluents should be documented on a separate stock record and should equal quantities of corresponding vaccines.

At the end of each month, determine the total number of vaccine and diluent doses used that month and the amount of stock still available. At the end of each year, use your stock record to determine the number of doses received for the year and add up your monthly dose counts to get a total number of doses used. This information will help you determine your facility's needs and guide you in ordering so you can minimize future waste and reduce the need for transfer and transport of vaccines. It will also help to make sure you have a sufficient supply to meet your patients' needs.

Vaccine Ordering

Order and stock only enough vaccine to meet patient needs.†

Storing a larger volume than your facility needs can increase the risk of wasting vaccines if they expire before they can be used or they are compromised in some way (e.g., due to mechanical failure of a storage unit).

Most facilities should also reorder based on patient needs after checking stock count. Vaccine orders usually arrive within one to two weeks, but there can be delays. When possible, avoid placing last-minute or rush orders to lessen the risk of running out of vaccines.

Arranging your stock

The vaccine coordinator (or other designated person) should rotate vaccine and diluent stock at least once a week, as well as each time your facility receives a vaccine delivery. This will ensure that vaccines expiring sooner are used first.

Stock Rotation and Removal

Vaccine stock should be rotated and checked for expired doses regularly. Any expired vaccines and diluents should be removed immediately to avoid inadvertently administering them. Arrange stock for each vaccine type so that doses with the earliest expiration dates are placed in front of those with later expiration dates.

Contact your immunization program* to find out if expired vaccines purchased with public funds can be returned.

*Contact your immunization program for details about specific state or local regulations impacting this activity.

†An adequate supply of vaccine varies for most providers, facilities, or immunization programs. It is recommended that reordering is done when stock has been reduced to a four week inventory.

Understanding Expiration Dates

Determining when a vaccine or diluent expires is a critical step in maintaining proper storage and handling. Understanding vaccine expiration dates can help save your practice time and money.

When the expiration date has only a month and year, the product may be used up to and including the last day of that month. If a day is included with the month and year, the product may only be used through the end of that day.

In some instances, such as the examples for beyond use date (BUD) below, vaccines must be used before the expiration date on the label.

Beyond Use Dates

Some vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first entered and the storage information in the package insert.

The BUD replaces the manufacturer's expiration date and should be noted on the label along with the initials of the person making the calculation. Examples of vaccines with BUDs include:

Reconstituted vaccines have a limited period for use once the vaccine is mixed with a diluent. This period or BUD is listed in the package insert.
Multidose vials might have a specified period for use once they have been entered with a needle. For example, the package insert may state that the vaccine must be discarded 28 days after it is entered. If the vial is entered on 06/01/2019, the BUD is 06/29/2019. The vaccine should not be used after the BUD.
Manufacturer-shortened expiration dates may apply when vaccine is exposed to inappropriate storage conditions. The manufacturer might determine the vaccine can still be used, but will expire on an earlier date than the date on the label.

Vaccine Disposal

General vaccine disposal guidelines for:

- **Expired or compromised vaccine**—sometimes unused vaccine and diluent doses, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded. Contact your immunization program* and/or the vaccine manufacturer for vaccine-specific information.
- **Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine predrawn by providers**—these cannot be returned and should be discarded according to your state requirements.
- **Empty vaccine vials**—most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.†† However, check and comply with your state requirements regarding disposal.

Medical waste disposal requirements may vary from state to state because they are set by state environmental agencies. Contact your immunization program* or state environmental agency for guidance to ensure your facility's vaccine disposal procedures comply with state and federal regulations.

*Contact your immunization program for details about specific state or local regulations impacting this activity.

††While vials are not usually considered hazardous or pharmaceutical waste, an empty RV dispensing tube or oral applicator is considered medical waste and should be disposed of in a medical waste container.

Preparing Vaccine for Administration

Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally as important as storing them properly.

Vaccine administration

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Only prepare vaccines when you are ready to administer them.
- Always check expiration dates and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration.

Different types of vaccine vials

Single-Dose Vials

A single-dose vial (SDV) contains one dose and should be used one time for one patient. SDVs do not contain preservatives to help prevent microorganism growth. Never combine leftover vaccine from one SDV with another to obtain a dose.

Only open an SDV when ready to use. Before you remove the protective cap, always check the vial to make sure you have the correct vaccine. Once you remove the cap, you must use the vaccine because it may not be possible to determine if the rubber seal has been punctured. Discard any unused SDVs without a protective cap at the end of the workday.

Multidose Vials

A multidose vial (MDV) contains more than one dose of vaccine. Because MDVs typically contain a preservative to help prevent the growth of microorganisms, they can be entered or punctured more than once. Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses have been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached.

MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a BUD noted in the package insert.

Never use partial doses from two or more vials to obtain a dose of vaccine.

Manufacturer-Filled Syringes

A manufacturer-filled syringe (MFS) is prepared and sealed under sterile conditions by the manufacturer. **Activate an MFS (i.e., remove the syringe cap or attach the needle) only when ready to use.**

An MFS does not contain a preservative to help prevent the growth of microorganisms. Once the sterile seal has been broken, the vaccine should be used or discarded by the end of the workday.

Reconstitution of Vaccine

Lyophilized (freeze-dried) vaccines are in either powder or pellet form and must be mixed with a liquid (diluent) in a process known as "reconstitution" before being administered.

Diluents vary in volume and composition and are specifically designed to meet volume, pH balance, and the chemical requirements of their corresponding vaccines. Refer to the manufacturer's package insert for guidance on storage and handling.

Diluents are not interchangeable unless specified by the manufacturer.

- Some diluents contain an antigen or an adjuvant needed for vaccine effectiveness. Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it.

Always check expiration dates on both diluents and vaccines before reconstituting them.†

Never use a stock vial of sterile water or normal saline to reconstitute vaccines.

Never administer vaccine reconstituted with the wrong diluent.

- If an incorrectly reconstituted vaccine has already been administered, contact your immunization program* or the vaccine manufacturer for revaccination guidance.

Predrawing Vaccine

Predrawing vaccines can result in waste if more are drawn up than needed.

Draw up vaccines only at the time of administration. Once vaccines are inside syringes, it is difficult to tell them apart, which can lead to administration errors. However, there may be rare instances when the only option is to predraw vaccine.

Predrawn syringes must be stored at the manufacturer-recommended temperatures throughout the clinic day. If vaccines must be predrawn:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Draw up vaccines only after arriving at the clinic site or mass vaccination event. Drawing up doses days or even hours before administering them is not a best practice because general-use syringes are not designed for storage.
- Each person administering vaccines should draw up no more than one MDV or 10 doses at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Predraw reconstituted vaccine into a syringe only when you are ready to administer it. If a predrawn vaccine is not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits. A manufacturer may specify that an unused reconstituted vaccine can only be stored in the vial for a specified amount of time.
- Discard any remaining vaccine in predrawn syringes at the end of the workday.

Never transfer predrawn reconstituted vaccine back into a vial for storage.

As an alternative to predrawing vaccines, use manufacturer-filled syringes for large vaccination clinics.

* Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

† If you are a VFC provider or have other vaccines purchased with public funds and must transfer vaccine to another facility so it can be used before it expires, contact your immunization program* for guidance on vaccine transport.

Transport, as described in this section, involves the movement of vaccine between providers or other locations over a shorter distance and time frame and is appropriate for events such as an emergency, off-site clinic, or to ensure vaccines that are about to expire can be used rather than wasted.

Vaccine Transport Situations

Vaccine transport to off-site or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and time frame for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised (e.g., because of power loss). Depending on the situation, some transport recommendations may be the same, but there are also some differences.

Vaccine Transport

Vaccines from your supply should not be routinely transported. In instances where the transport of vaccine from your supply is necessary, take appropriate precautions to protect your supply. Vaccines should only be transported using appropriate packing materials that provide the maximum protection.

Protecting your vaccine supply

- » Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility.
- » If delivery to the specific site is not possible, then vaccine can be transported in a stable storage unit and monitored with a TMD. If the facility doesn't have the capacity to refrigerate the vaccines, then a portable vaccine storage unit or qualified container and packout may be used with a DDL.
- » Develop an emergency plan or SOPs for transporting vaccines and include procedures and protocols for packing and transport.

Partially used vials cannot be transferred between providers OR across state lines.*

- **The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).**
- **Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.**
- **Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory. Appropriate materials include:**
  - Portable vaccine refrigerator/freezer units (preferred option)
  - Qualified containers and packouts
  - Hard-sided insulated containers or Styrofoam™ (Use in conjunction with the *Packing Vaccines for Transport during Emergencies*† tool. This system is only to be used in an emergency.)
  - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4° C to 5° C
  - Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
  - TMDs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

The same shipping materials the vaccines were initially shipped in should rarely, if ever, be used as they are not meant for reuse. This could put the cold chain and, ultimately, the viability of the vaccine, at risk.

* Contact your immunization program for details about specific state or local regulations impacting this activity.

† Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

Transport of Vaccines

It is always safest to have vaccines delivered directly to a facility with a vaccine storage unit ready to receive the shipment, but this is not always possible. If necessary, vaccines may be transported using a portable vaccine refrigerator with a temperature monitoring device placed with the vaccines. If a portable vaccine refrigerator is not available, qualified containers and packouts with a TMD in each container can be used. For transport to an off-site clinic, bring only what is needed for the workday.

Transport System Recommendations

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System†	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Coolants for Transport

PCMs at 4° C–5° C (39° F–41° F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions‡ for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be "sweating."

In emergency situations, a system using conditioned water bottles can be used. Manufacturers' original shipping containers may also be used as a last resort in an emergency situation.

The *Packing Vaccines for Transport during Emergencies*† tool describes a system in which properly conditioned frozen water bottles can be used as a coolant when transporting vaccine during emergency situations.

Transport Planning and Preparation

Improper packing for transport is as risky for vaccines as a failed storage unit.

Include vaccine packing and transport protocols in your routine and emergency storage and handling SOPs. At a minimum, include the following procedures and protocols:

For all staff-facilitated transport:

- Identify trained staff to pack vaccines as well as primary and backup vehicles and drivers for transport in advance.
- Consider renting a refrigerated truck if you have a large quantity of vaccines or need to transport vaccines an extended distance.
- Take an inventory of your vaccines and record actions to protect the vaccines during transport.
- Open unit doors only when necessary and only after completing all preparation for packing and moving vaccines.

Emergency Transport

In addition to the actions outlined in Transport Planning and Preparation, during an emergency also:

» Contact the alternative vaccine storage facility before packing any vaccine to confirm it can accept your vaccines for storage.

» Note any protective measures in place at the time of the event (water bottles, battery-powered TMD, transport to alternative facility, etc.).

» Only open the unit door when you are ready to pack or power has been restored.

» If an emergency can be anticipated (e.g., weather event), suspend vaccination activities before the onset of emergency conditions to allow more time for packing and transport.

†Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

‡Manufacturers' vaccine package inserts: www.immunize.org/fda/

- If using a company or personal vehicle, only transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Move transport containers directly to a vehicle that is already at a comfortable temperature, neither too hot nor too cold.
- Avoid leaving containers in areas where they are exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.
- Check with your immunization program[§] for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

Transporting Opened Multidose Vials

If absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, **a partially used vial cannot be transferred from one provider to another or across state lines.**

Transporting Diluents

Transport diluents with their corresponding vaccines so there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance[‡] for specific temperature requirements.

If diluents stored at room temperature (20° C to 25° C [68° F to 77° F]) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

Never freeze diluents—not even during transport.

Place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

Transporting Frozen Vaccines

If frozen vaccines must be transported, use a portable vaccine freezer unit or qualified container and packout that maintains temperatures between -50° C and -15° C (-58° F and +5° F).

Follow these steps for transporting frozen vaccines:

- Place a TMD (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -50° C and -15° C (-58° F and +5° F) . Any stand-alone freezer that maintains these temperatures is acceptable.
- Record the time vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.

Do not use dry ice, even for temporary storage. Dry ice might expose the vaccines to temperatures colder than -50° C (-58° F).

Temperature Monitoring During Transport

Use a continuous TMD, preferably a DDL, for monitoring and recording temperatures while transporting vaccines:

- The TMD should have an accuracy of +/-0 .5° C (+/-1° F).
- Place buffered probe material in a sealed vial directly with the vaccines.
- Keep the TMD display on top of vaccines so you can easily see the temperature.

[§]Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

[‡]Manufacturers' vaccine package inserts: www.immunize.org/fda/

Temperature Monitoring After Transport

Immediately upon arrival at the destination, vaccines should be stored in an appropriate storage unit with a TMD. Be sure to follow these guidelines for monitoring and recording storage unit temperature:

- If the device displays min/max temperatures, this information should be checked and recorded.
- If the device does not display min/max temperatures, then the current temperature should be checked and recorded a minimum of two times (at the start and end of the workday).

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine storage unit using the following guidance:

- Place a TMD (preferably with a probe in a thermal buffer) as close as possible to the vaccines, and check and record temperatures hourly.
- Keep the container closed as much as possible.
- For off-site clinic use, remove only one multidose vial or 10 doses at a time for preparation and administration by each person administering vaccines.

SECTION SEVEN: Emergency Vaccine Storage and Handling

Emergencies like equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, you should make additional plans to prepare for emergencies.*

Emergency Equipment Backup Options

Alternative Storage Facility

No piece of vaccine storage equipment is infallible. At some point, equipment will fail because of a power outage, breakdown, or normal wear and tear.

- **Establish a working agreement with at least one alternative storage facility even if you have a generator as backup equipment.** Make sure you have 24-hour access to this facility. Hospitals, long-term care facilities, state depots, the Red Cross, fire stations, packing plants, and commercial pharmacies are some of the facilities that may be able to assist you.

Your facility may also choose to have a backup storage unit so that vaccine may not have to be packed and/or moved to an alternative storage facility if the primary storage unit fails.

Accessing Your Building after Hours

Emergency situations can arise outside of normal business hours, so maintain a relationship with your facility's building manager and/or security staff. Ensure all staff members are familiar with emergency SOPs, including after-hours roles and responsibilities. **Your facility's storage and handling SOPs should include instructions for accessing your vaccine storage units when the building is closed with a building map/diagram and locations of:**

- Spare batteries
- Flashlights
- Keys
- Locks
- Circuit breakers
- Emergency transport equipment and materials

Keep information on after-hours building access and security procedures with the SOPs, with building management and security staff, if appropriate, and also make sure relevant staff has copies of this information available at home.

Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor your DDL to determine when additional action should be taken.

Generators and backup battery power sources

Having an on-site generator(s) prevents the need to transport vaccines to an alternative storage facility during a power outage.

» Keep sufficient fuel on hand to continuously run the generator for at least 72 hours.

» A generator should be tested quarterly and serviced annually.

A backup battery power source can be used in lieu of a generator.

» Backup battery power sources should be tested quarterly and serviced annually.

» Check the manufacturer's guide for testing procedures and maintenance schedules.

If an alternative vaccine storage facility is not available

If you cannot find an alternative vaccine storage facility within a reasonable distance, or if you cannot reach your alternative facility, you can use qualified containers and packouts and portable vaccine refrigerator/freezer units (if power source is available) using the *Packing Vaccines for Transport during Emergencies system*. Always place a TMD with the vaccines and carefully monitor the TMD to ensure vaccines remain within the appropriate temperature range. Temporary storage containers should remain closed, and vaccines can only be stored safely for as long as the containers are validated to maintain proper storage temperatures.

*The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm.

Power Outages

Monitoring Unit Temperature during a Power Outage

If your storage unit has an external temperature monitoring display that you can check without opening the unit door, take the following steps:

- Record room temperature (if possible) and the temperature inside the unit as soon as the power goes out.
- Record minimum and maximum temperatures reached inside the unit during the outage.
- Temperature excursions should be avoided, if possible, by using emergency plans and SOPs for transport and alternative storage. However, if temperatures have fallen outside of the recommended range, follow your procedures for temperature excursions.

If you cannot monitor the temperature inside the unit without opening the door and you do not have an alternative facility with power where the vaccines can be stored or other emergency vaccine storage SOPs, wait until power is restored and then take the following steps:

- Record the room temperature (if possible) and the temperature inside the unit.
- If using a DDL, document the length of time the power was off and the minimum and maximum temperatures during that period.
- If temperatures inside the unit have already fallen outside of the recommended range, follow your procedures for temperature excursions. Even if an excursion has occurred, move your vaccines to an alternative storage unit or location where they can be stored at appropriate temperatures, if possible. Make sure to separate and mark these vaccines "Do NOT Use" until a decision can be made about whether the vaccines can still be used.

During a power outage, only open the storage unit door if:

» Power is restored.

» It is determined that the vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility.

Glossary

Buffered temperature probe	Temperature probe designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is "buffered" 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®, aluminum).
Beyond use date (BUD)	The date or time after which a vaccine should not be administered, stored, or transported. The BUD should never exceed the manufacturer's original expiration date.
Calibration	Professional measurement of the accuracy of a temperature monitoring device's readings against nationally accepted standards.
Cold chain monitor (CCM)	Generally, a single-use device that monitors the temperature inside a vaccine shipping container. CCMs should be thrown away after being checked. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer).
Conditioned water bottles	Frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.
Digital data logger (DDL)	An electronic device that records data digitally over time or in relation to location either with a built-in or external instrument or sensor.
Diluent	A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of these vaccines also supply the matching diluent.
Dormitory-style (bar-style) storage unit	A combination refrigerator/freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.
Fan-forced air circulation	Technology using powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery.
Household-grade storage unit	A storage unit that is primarily sold for home use.
Lyophilized	Freeze-dried; usually referring to a vaccine that is freeze-dried into a powder or wafer.
Minimum/maximum temperature	A vaccine storage unit's coldest and warmest temperature readings during a set period of time.

Glossary

Phase change materials (PCMs)	Engineered packing supplies that help control container temperatures during vaccine transport or shipping.
Potency	A vaccine's strength or effectiveness; in the context of this toolkit, potency refers to a vaccine's response to environmental conditions.
Presentation	Type of packaging for a vaccine (e.g., single-dose vial, multidose vial, manufacturer-filled syringe, etc.).
Purpose-built /pharmaceutical-grade units	Units that are specifically designed to store vaccines.
Qualified container and packout	A type of container and supplies specifically designed for use when packing vaccines for transport. They are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.
Standard operating procedures (SOPs)	A set of step-by-step instructions compiled by an organization to help workers carry out complex routine or emergency operations. SOPs aim to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and preventing failure to comply with industry regulations and best practices.
Stand-alone storage unit	A storage unit that operates independently of any other device or system for its desired function (i.e., a refrigerator that only functions as a refrigerator or a freezer that only functions as a freezer).
Temperature excursion	Any temperature reading that is outside the recommended range for vaccine storage as defined by the manufacturer's package insert.
Tolerance	Compliance with nationally accepted standards for the calibration limits of temperature monitoring equipment. The equipment can either be considered "in" or "out" of tolerance.
Traceability	An unbroken chain of measurements and associated uncertainties.
Uncertainty	The quantification of the doubt about the measurement result.

REFERENCE: Purpose-Built Vaccine Storage Units

Numerous vaccine storage units have entered the market that are designed specifically for the storage of vaccines. These units can take many physical forms. Some look like traditional stand-alone units, while others can take the form of dispensing or vending units, either with or without doors. Although these units may be similar to pharmaceutical-grade or medical-grade units, they are unique in that they are designed and tested to keep vaccines in appropriate storage conditions. If you are a VFC provider, your immunization program determines which purpose-built units meet VFC program requirements. Always check with your immunization program before purchasing any unit that will be used to store VFC vaccines. Features and considerations related to these types of units include the following:

VFC Vaccine Management

- Purpose-built units must have the ability to allow the user to separate public and private vaccine stock physically or virtually
- If stock is separated virtually, an inventory printout† must be accessible upon request.
- If unable to physically remove expired vaccine from a purpose-built unit immediately, the unit must be able to make expired vaccine inaccessible.

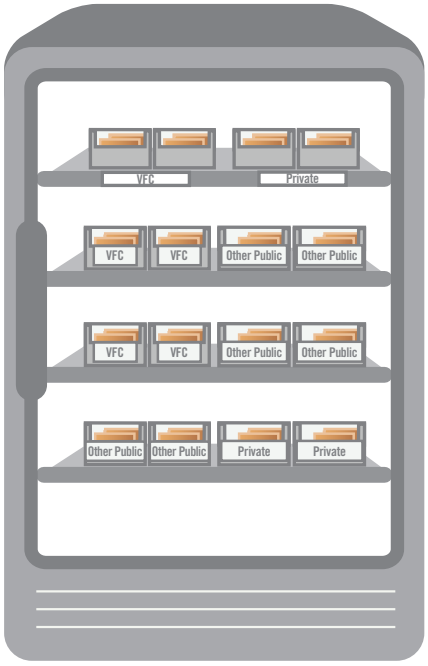
†The inventory printout should be used to answer storage and handling and inventory sections of the site visit reviewers guide.

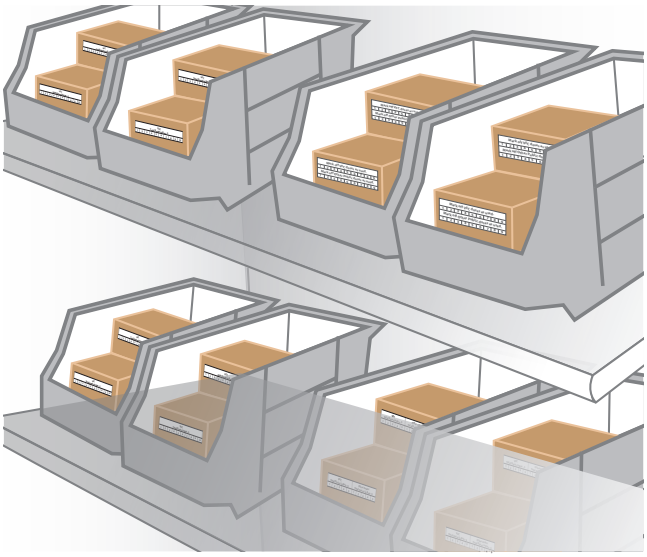
Temperature Monitoring

- Many purpose-built units have multiple temperature probes or sensors. It is important that these probes or sensors have current Certificates of Calibration.
- Many of the purpose-built closed or doorless units may utilize air sensors (non-buffered probes). Since these units have very limited exposure to ambient air, the use of a buffered probe is not essential.
- Many purpose-built units will have built-in digital data loggers with electronic interfaces that will allow you to track the continuous temperatures and/or provide min/max temperatures. If you are a VFC provider, always check to make sure that these satisfy the VFC program data logger requirements.

Vaccine Storage

- Many purpose-built units have undergone testing and temperature mapping so that the probe is in the most appropriate location.
- Although purpose-built units can have multiple temperature probes, a backup DDL is still needed for transport to a backup facility in an emergency.
- Many purpose-built units do not need water bottles to serve as thermal ballast.





WORKSHEET: Vaccine Storage and Handling SOPs

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit.

CHECKLIST OF GENERAL INFORMATION

» Up-to-date contact information
- Primary vaccine coordinator
- Alternate vaccine coordinator
- Additional staff to assist in emergencies
- Immunization program
- Vaccine manufacturers
- Refrigerator and freezer maintenance and repair companies
- Temperature monitoring device (TMD) companies
- Utility/power company
- Vaccine storage unit alarm company (if applicable)
- Generator repair company (if applicable)
- Sources for qualified containers and packouts

» Descriptions of the roles and responsibilities of the primary and alternate vaccine coordinators

» Information for each storage unit, including serial number, links to equipment websites, installation dates, and routine maintenance and repair records

» Samples of all vaccine-related forms used in your facility

» Protocols for staff education and training

CHECKLIST FOR ROUTINE STORAGE AND HANDLING

Protocols for:
- Ordering and accepting vaccine deliveries
- Unpacking deliveries
- Managing inventory
- Storing each vaccine and diluent
- Placing vaccines and diluents in storage units
- Handling vaccines prior to administration
- Disposing of vaccines and supplies
- Monitoring storage unit and temperature
- Maintaining storage equipment and TMDs
- Responding to storage and handling problems
- Transporting vaccines to off-site/satellite facilities

CHECKLIST FOR EMERGENCY VACCINE STORAGE, HANDLING, AND TRANSPORT

All contact information in Checklist for General Information as well as up-to-date contact information for:
- Alternative vaccine storage facility (one or more)
- Transportation of vaccines

Vaccine storage unit specifications (type, brand, model number, serial number)

Diagram of facility showing important elements, including doors, flashlights, packing materials, batteries, circuit breakers

Keep a copy of emergency SOPs with emergency supplies and at multiple off-site locations such as homes of vaccine coordinator and alternate coordinator and with building manager, security staff, and alternative storage facility.

Protocols for:
- Monitoring vaccines during a power outage
- Packing vaccines and diluents for emergency transport
- Transporting vaccines to and from an alternative vaccine storage facility
- Assessing whether vaccine can be used after an emergency
- Accessing your building and facility after hours

WORKSHEET: Vaccine Storage and Handling SOPs

Store emergency information with emergency supplies.

STAFF CONTACT LIST			
Name	Title	Telephone Numbers home/cell/other	E-mail Address
	Primary Vaccine Coordinator		
	Alternate Vaccine Coordinator		

EMERGENCY STAFF CONTACT LIST			
Name	Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			

List contacts in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient.

WORKSHEET: Vaccine Storage and Handling SOPs

GENERAL RESOURCES CONTACT LIST			
Resources	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Local Health Department Immunization Program			
State Health Department Immunization Program			
Vaccine Manufacturers			
Refrigerator Repair Company			
Freezer Repair Company			
Utility/Power Company			
Temperature Monitoring Device Company			
Vaccine Storage Unit Alarm Company (if applicable)			
Generator Repair Company (if applicable)			

ALTERNATIVE VACCINE STORAGE FACILITIES			
Alternative Vaccine Storage Facility Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			

TRANSPORTATION TO ALTERNATIVE VACCINE STORAGE FACILITIES			
Emergency Resources Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Refrigeration Company			
Refrigeration Company (alternative)			
Private Vehicle			
Private Vehicle (alternative)			

WORKSHEET: Vaccine Storage and Handling SOPs

PACKING MATERIAL SUPPLIERS CONTACT LIST

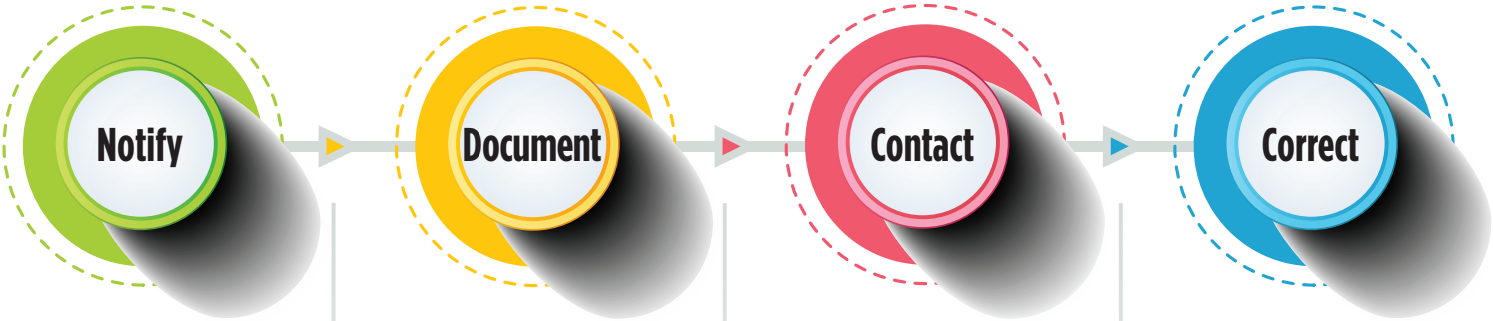
Emergency Resources	Company Name	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Portable vaccine refrigerator/freezer units				
Qualified containers and packout materials				
Qualified containers and packout materials (alternative)				
Packing materials				
Packing materials (alternative)				

VACCINE STORAGE UNIT SPECIFICATIONS

Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



Notify

» Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.

» Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document

» Document details of the temperature excursion:

- Date and time
- Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
- Room temperature, if available
- Name of the person completing the report
- General description of the event (i.e., what happened)
- If using a digital data logger (DDL), determine the length of time vaccine may have been affected
- Inventory of affected vaccines
- List of items in the unit other than vaccines (including water bottles)
- Any problems with the storage unit and/or affected vaccines before the event
- Other relevant information

Contact

» Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).

» Be prepared to provide the immunization program or manufacturer with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:	
Dynavax	1-844-375-4728
GlaxoSmithKline	1-888-825-5249
Massachusetts Biological Labs	1-888-825-5249
MedImmune	1-877-633-4411
Merck	1-800-672-6372
Pfizer	1-800-438-1985
Sanofi Pasteur	1-800-822-2463
Seqirus	1-855- 358-8966

Correct

» If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.

» Check the basics, including:

- Power supply
- Unit door(s)
- Thermostat settings

» If the excursion was the result of a temperature fluctuation, refer to the section, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's Vaccine Storage and Handling Toolkit for detailed guidance on adjusting storage unit temperature to the appropriate range.

» If you believe the storage unit has failed, implement your emergency vaccine storage and handling SOPs. Never allow vaccines to remain in a nonfunctioning unit following a temperature excursion.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

°F	°C	°F	°C	°F	°C
-22	-30	**21**	-6.1	**64**	17.8
-21	-29.4	**22**	-5.6	**65**	18.3
-20	-28.9	**23**	-5	**66**	18.9
-19	-28.3	**24**	-4.4	**67**	19.4
-18	-27.8	**25**	-3.9	**68**	20
-17	-27.2	**26**	-3.3	**69**	20.6
-16	-26.7	**27**	-2.8	**70**	21.1
-15	-26.1	**28**	-2.2	**71**	21.7
-14	-25.6	**29**	-1.7	**72**	22.2
-13	-25	**30**	-1.1	**73**	22.8
-12	-24.4	**31**	-0.6	**74**	23.3
-11	-23.9	**32**	0	**75**	23.9
-10	-23.3	**33**	0.6	**76**	24.4
-9	-22.8	**34**	1.1	**77**	25
-8	-22.2	**35**	1.7	**78**	25.6
-7	-21.7	**36**	2.2	**79**	26.1
-6	-21.1	**37**	2.8	**80**	26.7
-5	-20.6	**38**	3.3	**81**	27.2
-4	-20	**39**	3.9	**82**	27.8
-3	-19.4	**40**	4.4	**83**	28.3
-2	-18.9	**41**	5	**84**	28.9
-1	-18.3	**42**	5.6	**85**	29.4
0	-17.8	**43**	6.1	**86**	30
1	-17.2	**44**	6.7	**87**	30.6
2	-16.7	**45**	7.2	**88**	31.1
3	-16.1	**46**	7.8	**89**	31.7
4	-15.6	**47**	8.3	**90**	32.2
5	-15	**48**	8.9	**91**	32.8
6	-14.4	**49**	9.4	**92**	33.3
7	-13.9	**50**	10	**93**	33.9
8	-13.3	**51**	10.6	**94**	34.4
9	-12.8	**52**	11.1	**95**	35
10	-12.2	**53**	11.7	**96**	35.6
11	-11.7	**54**	12.2	**97**	36.1
12	-11.1	**55**	12.8	**98**	36.7
13	-10.6	**56**	13.3	**99**	37.2
14	-10	**57**	13.9	**100**	37.8
15	-9.4	**58**	14.4	**101**	38.3
16	-8.9	**59**	15	**102**	38.9
17	-8.3	**60**	15.6	**103**	39.4
18	-7.8	**61**	16.1	**104**	40
19	-7.2	**62**	16.7		
20	-6.7	**63**	17.2		

°C	°F	°C	°F
-30	**-22**	13	**55.4**
-29	**-20.2**	14	**57.2**
-28	**-18.4**	15	**59**
-27	**-16.6**	16	**60.8**
-26	**-14.8**	17	**62.6**
-25	**-13**	18	**64.4**
-24	**-11.2**	19	**66.2**
-23	**-9.4**	20	**68**
-22	**-7.6**	21	**69.8**
-21	**-5.8**	22	**71.6**
-20	**-4**	23	**73.4**
-19	**-2.2**	24	**75.2**
-18	**-0.4**	25	**77**
-17	**1.4**	26	**78.8**
-16	**3.2**	27	**80.6**
-15	**5**	28	**82.4**
-14	**6.8**	29	**84.2**
-13	**8.6**	30	**86**
-12	**10.4**	31	**87.8**
-11	**12.2**	32	**89.6**
-10	**14**	33	**91.4**
-9	**15.8**	34	**93.2**
-8	**17.6**	35	**95**
-7	**19.4**	36	**96.8**
-6	**21.2**	37	**98.6**
-5	**23**	38	**100.4**
-4	**24.8**	39	**102.2**
-3	**26.6**	40	**104**
-2	**28.4**		
-1	**30.2**		
0	**32**		
1	**33.8**		
2	**35.6**		
3	**37.4**		
4	**39.2**		
5	**41**		
6	**42.8**		
7	**44.6**		
8	**46.4**		
9	**48.2**		
10	**50**		
11	**51.8**		
12	**53.6**		

SAMPLE: Stock Record and Tally Sheet

STOCK RECORD

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: PPSV23 Month and Year: August 2018

Date Received or Usage Tallied	Person Receiving Shipment*	Arrival Condition**	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used†	Balance (Doses)††
08/02/18	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/18										1	1
08/15/18	LST	G	PPSV23	Merck	MDV	03958	02/15/19	N/A	5	3	3
08/23/18										1	2
08/29/18										0	2
								Vaccine Totals	7	5	2

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival
** G = vaccines/diluents arrived in good condition
? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.
*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacturer-filled syringe
† Includes number of doses administered, wasted, unusable, expired, or transferred.
†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Physical Stock Check (In Doses)	2
Difference ("Balance" minus Physical Stock)	0
Balance Carried Forward (In Doses)	2

Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an immunization information system (IIS), this stock record may be used.

TALLY SHEET

Instructions: Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: August 19—23, 2018 (Week 3)

Storage Location (R or F)*	Vaccine or Diluent Name	Doses Administered		Doses Wasted	Doses Expired	Doses Unusable**	Doses Transferred (Viable)***	Total
F	VAR	𝍸 III	(8)					8
R	DTaP	𝍸 𝍸 II	(12)					12
R	HepB	𝍸 𝍸 II	(12)					12
R	IPV	𝍸 𝍸 II	(12)		II			14
R	HepA (pediatric)	II	(2)					2
R	PPSV23	I	(1)					1

* R = Refrigerator F = Freezer
** Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.
*** Viable vaccine doses transferred to your state or local health department immunization program or another facility.

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used.

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: _____ Month and Year: _____

Date Received or Usage Tallied	Person Receiving Shipment*	Arrival Condition**	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used†	Balance (Doses)††
	BEGINNING BALANCE FOR THE MONTH									**N/A**	

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival

** G = vaccines/diluents arrived in good condition
? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.

*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacturer-filled syringe

† Includes number of doses administered, wasted, unusable, expired, or transferred.

†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Vaccine Totals	
Physical Stock Check (In Doses)	
Difference ("Balance" minus Physical Stock)	
Balance Carried Forward (In Doses)	

Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an immunization information system (IIS), this stock record may be used.

Tally Sheet

Instructions: Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: _____

Storage Location (R or F)*	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired	Doses Unusable**	Doses Transferred (Viable)***	Total

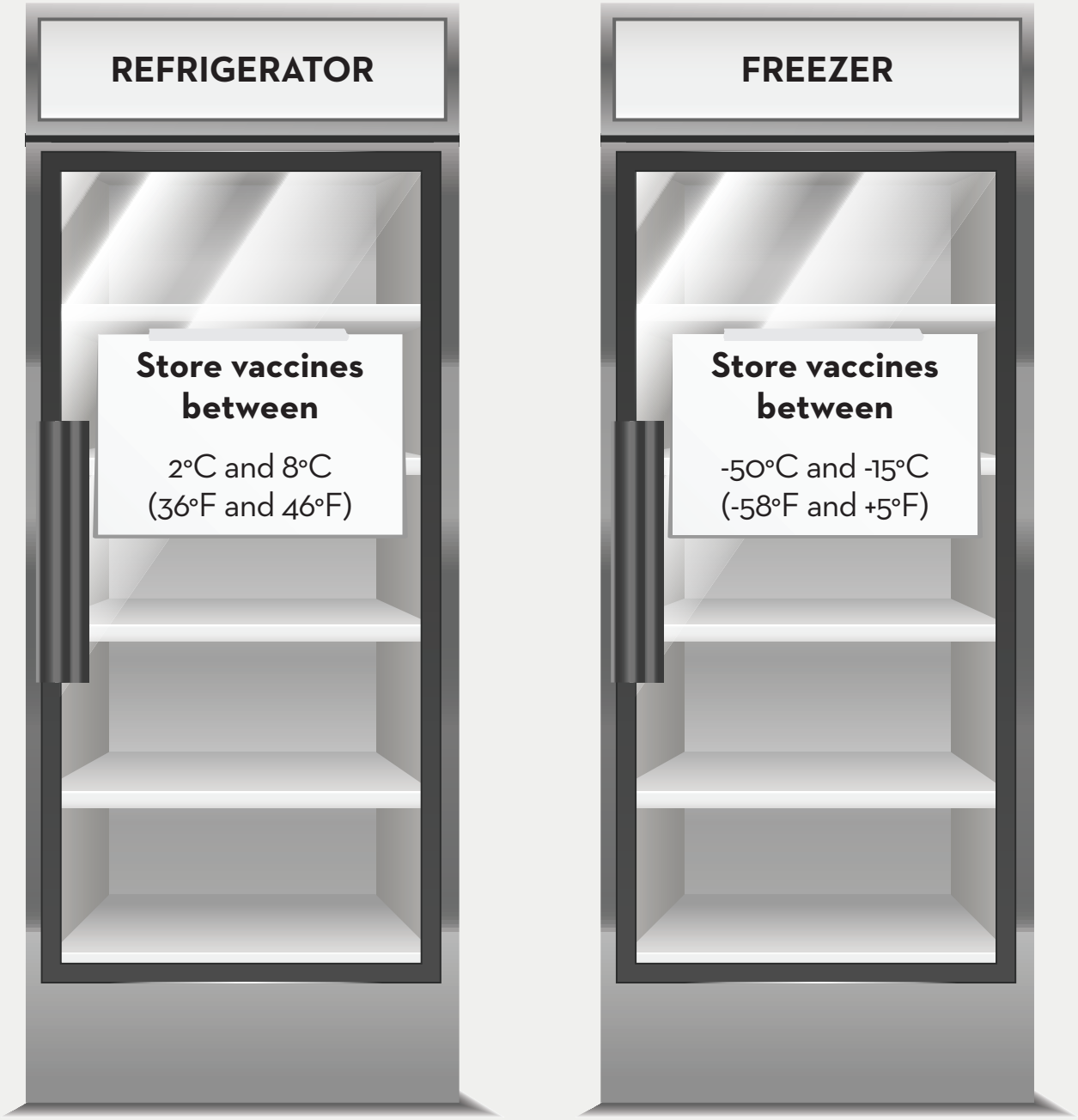
* R = Refrigerator F = Freezer

** Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

*** Viable vaccine doses transferred to your state or local health department immunization program or another facility.

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used.

HANDLE WITH CARE: Protect Your Vaccine | Protect Your Patients



- Keep your storage units and vaccines within the appropriate temperature ranges.
- Check and record storage unit min/max temperatures at start of each workday. If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday). Also check current temperature before accessing and administering vaccine.
- Take immediate action if temperatures are out of range.
- Keep vaccines in their original packages.
- Many vaccines should be protected from light (consult manufacturer's product information).
- Check expiration dates and rotate your vaccine stock to keep most recent expiration dates at the front.

WARNING LABELS: Do Not Adjust Refrigerator Controls

STOP

Do **NOT** adjust refrigerator or freezer temperature controls!

Notify _____/_____
(insert name/phone number)

if adjustment is necessary.

ALTO

¡ NO cambie la temperatura del refrigerador/congelator!

Comuníquese con

_____/_____
(inserte nombre y número de teléfono aqui)

si hay necesidad de cambiar la temperatura.

WARNING LABELS: Do Not Adjust Freezer Controls

STOP

Do **NOT** adjust
FREEZER
temperature controls!

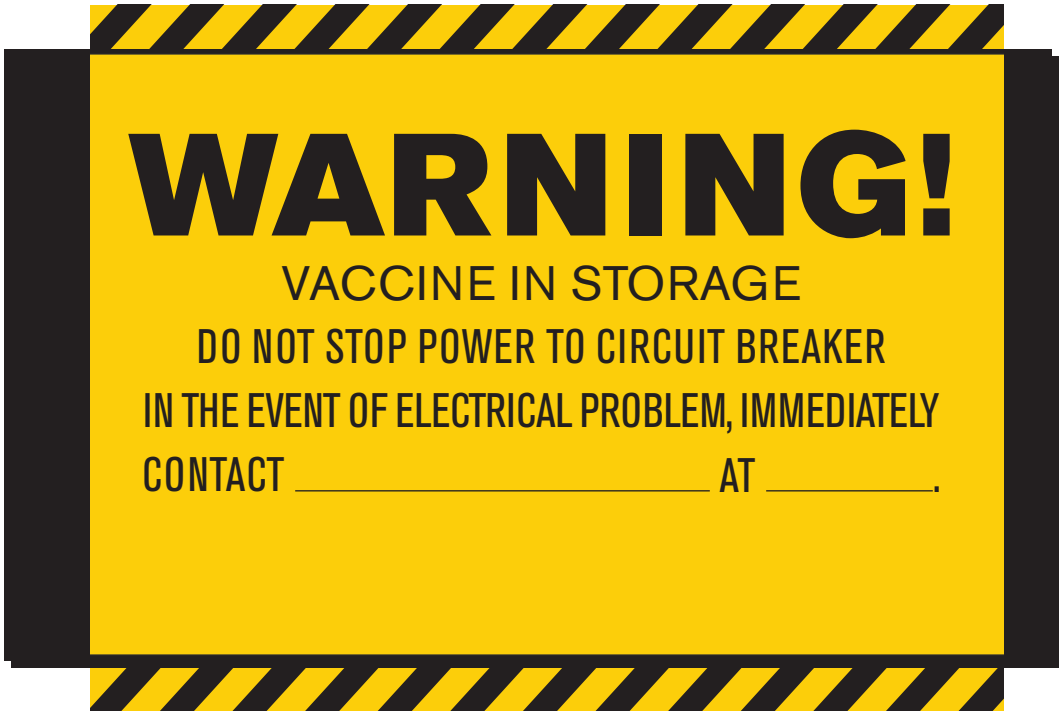
Notify _____/_____
(insert name/phone number)
if adjustment is necessary.

ALTO

¡ NO cambie la
temperatura del
CONGELATOR!

Comuníquese con
_____/_____
(inserte nombre y número de teléfono aqui)
si hay necesidad de
cambiar la temperatura.

WARNING LABELS: Warning! Do Not Stop Power to Circuit Breaker



WARNING LABELS: Warning! Do Not Unplug Refrigerator

WARNING!

DO **NOT** UNPLUG THE **REFRIGERATOR** OR BREAK CIRCUIT.

VACCINE IN STORAGE.

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY CONTACT: _____/_____.

(insert name/phone number)

¡AVISO!

NO DESCONECTE EL **REFRIGERADOR** NI CORTE EL CIRCUITO.

¡CONTIENE VACUNAS!

SI HAY UN PROBLEMA CON LA ELECTRICIDAD, COMUNIQUESE INMEDIATAMENTE CON:

_____.

(inserte nombre y número de teléfono aqui)

WARNING LABELS: Warning! Do Not Unplug Freezer

WARNING!

DO **NOT** UNPLUG THE **FREEZER** OR BREAK CIRCUIT.

VACCINE IN STORAGE.

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY CONTACT: _____/_____.

(insert name/phone number)

¡AVISO!

NO DESCONECTE EL **CONGELADOR** NI CORTE EL CIRCUITO.

¡CONTIENE VACUNAS!

SI HAY UN PROBLEMA CON LA ELECTRICIDAD, COMUNIQUESE INMEDIATAMENTE CON:

_____/_____.

(inserte nombre y número de teléfono aqui)

TRANSPORT LABELS: Refrigerate/Freeze Upon Arrival

TRANSPORT LABELS: Open Immediately: Refrigerate/Freeze Upon Receipt

TRANSPORT LABELS: Fragile: Handle with Care

TRANSPORT LABELS: Perishable: Rush

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Drug and Hazardous Substance Disposal		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL CAL-OSHA standards and 29 CFR 1910.1030.		

Purpose:

Site has method(s) in place for drug and hazardous substance disposal.

Definition:

Hazardous substance – Substances that are physical or health hazards

- Examples of physical hazard include substances that are:
  - Combustible liquid, compressed gas, explosive, flammable, organic peroxide, oxidizer, pyrophoric, unstable or water reactive.
- Examples of health hazard include substances where acute or chronic health effects may occur with exposure such a:
  - Carcinogens, toxic or highly toxic agents, irritant, corrosives, sensitizers, and agents that damage the lungs, skin, eyes, or mucus membranes

Note: All drugs that are unused are considered by the EPA to be toxic wastes and must be disposed in accordance with 40 CFR, part 261)

Policy:

- Safety practices on site are followed in accordance with current/updated CAL-OSHA standards and 29 CFR 1910.1030.
- Hazardous materials are kept in lockable storage area inaccessible to patients.
- The manufacturer's label is not removed from a container (bag, bottle, box, can, cylinder, etc.) only if the hazardous material or residues of the material remain in the container.

- Containers for biohazard waste shall comply with United States Department of Transportation requirements when prepared for transport offsite from the facility.
- A hazardous waste transporter transporting medical waste shall maintain a completed tracking document and provide a copy of that document to the medical waste generator (clinic, etc.).
- All portable containers of hazardous chemicals and secondary containers require labeling. All substances are appropriately labeled with the following information (see Appendix A)
    - Identity of hazardous substance
    - Description of hazard warning: can be words, pictures, symbols
    - Date of preparation or transfer
- Retain receipts from Medical Waste Hauler Company: _____

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

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.

Appendix A


HAZARDOUS WASTE
ACCUMULATION START DATE:
EPA WASTE CODES:
GHS PICTOGRAMS
Select applicable pictograms
HANDLE WITH CARE!
HAZARDOUS PROPERTIES
☐ FLAMMABLE ☐ CORROSIVE
☐ TOXIC ☐ REACTIVE
CONTENT COMPOSITION – ☐NEW ☐USED
%

Preparing Vaccine Storage Units

Prepare vaccine refrigerators and freezers to maintain stable temperatures. Stabilize temperatures before storing vaccines. The concepts are identical for both refrigerators and freezers.

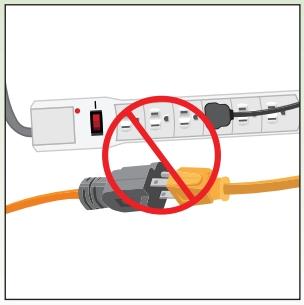
1. Protect the power supply.

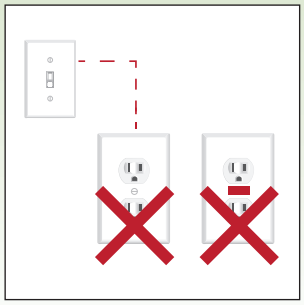
DO

- Plug each storage unit into its dedicated wall outlet.
- Secure the plug with a guard or cover and post "Do Not Unplug" signs.
- Label fuses and circuit breakers so the Vaccine Coordinator is alerted if power goes off.

DO NOT USE

- Multi-outlet power strips or extension cords
- Outlets with GFI circuit switches (they have red reset buttons)
- Outlets that are controlled by wall switches





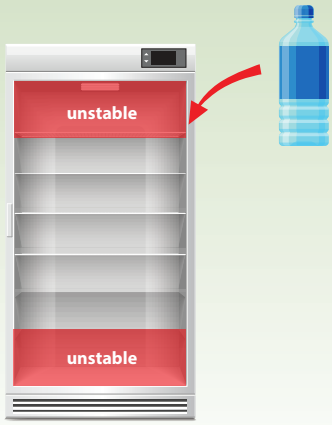
2. Add plenty of water bottles (refrigerators) or cold packs (freezers only) in unstable areas:

- On the top shelf (don't block air vents)
- On the unit's floor (for household stand-alone units, remove drawers and bins)
- In any door shelves

Tip: Add them along the back wall to prevent vaccines from touching the wall.

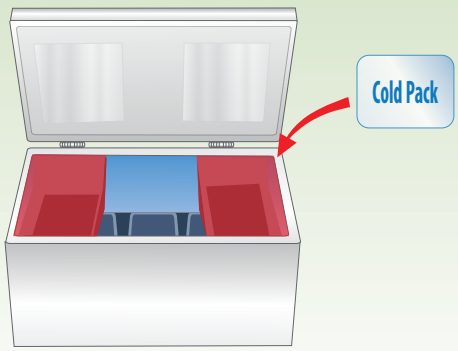
Refrigerators

Household-grade



Pharmaceutical-grade

Chest freezer



www.eziz.org

Preparing Vaccine Storage Units

3. Set up a data logger for each storage unit.

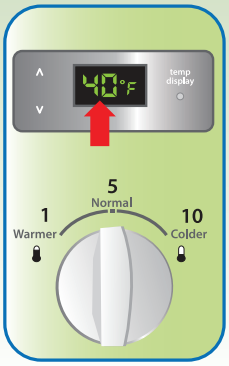
- Place the buffered probe in the center of the storage unit next to vaccines.
- Place or mount the digital display so temperatures can be read without opening the storage unit door.
- Thread the probe's cable through the side of the door and attach it to the digital display.
- Store your backup device's buffered probe in the vaccine refrigerator.

4. Ensure the data logger is recording.

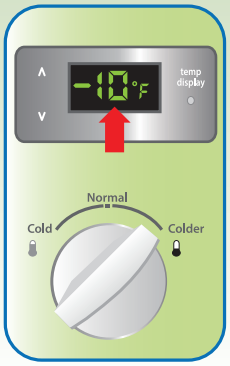
Tip: Some devices might display "REC" or "RECORDING."

5. Set storage unit temperatures.

For refrigerators.
Set thermostat to 40°F (4°C). If it has a dial, adjust the temperature dial as needed.

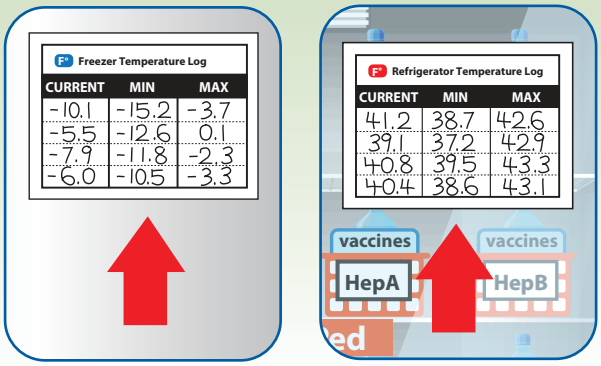


For freezers.
Set thermostat to below 0°F (18°C). If it has a dial, set it to the coldest.



6. Post VFC temperatures logs.

Post VFC temperature logs on the refrigerator and freezer doors.
Once temperatures have stabilized, record CURRENT, MIN, and MAX temperatures on the logs twice daily.



While Waiting for Temperatures to Stabilize

7. Configure data logger settings using VFC's "Data Logger Setup & Use" job aid.

8. Set up storage units using VFC's "Setting Up Vaccine Storage Units" job aid.

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Drug Expiration Protocol		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Establish a procedure to check expiration dates of all drugs (including vaccines and samples), and infant and therapeutic formula at least monthly.

Definition:

Expiration Date — The expiration date identifies the time during which medications may be expected to meet the requirements of the Pharmacopeia monograph, provided it is kept under the prescribed storage conditions.

Policy:

The manufacturer's expiration date must appear on the labeling of all drugs. All prescription, sample and over-the-drugs not bearing the expiration date are deemed to have expired. Expired drugs may not be distributed or dispensed. If a drug is to be reconstituted at the time of dispensing, its labeling must contain expiration information for both the reconstituted and un-reconstituted drug.

Procedure:

Specified staff will maintain Monthly Equipment, Medication Verification and Replacement Logs. (See Appendix A)

All medications (vaccinations, prescription, sample or over-the-counter) will be verified monthly. Any expired drugs will be removed, properly disposed of and replaced.

Any medication vials should be discarded whenever sterility is compromised or questionable. If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different date for the opened vial.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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Appendix A

MONTHLY EQUIPMENT, MEDICATION VERIFICATION AND REPLACMENT LOG

YEAR_ _ _ _

Instructions: Document day of month and initials when equipment is verified to be in working order, medications are within expiration dates, oxygen tank is full and Medication dosage chart is present. Please initial each category as you check the medication and equipment.

An initial indicates that the items have been checked; expired medications and lab supplies purged, properly disposed of, and replaced.

Month/Date	Meds, In Refrigerator Freezer	All other meds and samples	Emergency Equipment/ Medication used and Replaced	Oxygen level, key, mask, and tubing attached	All Lab reagents, hemocults etc.	All vacutainers, tubes, culture medium & collection system	Other
January							
February							
March							
April							
May							
June							
July							
August							
September							
October							
November							
December							

Initials	Signature	Initials	Signature

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Preparing and Confirming Vaccine/Medication Prior to Administration		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL CMS Manual System; 42 CFR 482.23© 40 CFR, part 261		

Purpose:

- To ensure proper preparation in order to maintain the integrity of the vaccine/medication during transfer from the vial to the syringe and that vaccines/medications are prepared and drawn only prior to administration.
- Proper vaccine/medication administration is critical to ensure that the vaccination/medication is safe and effective.
- To ensure vaccine/medication administration is performed by personnel within their Scope of Practice.
- To verify that personnel are able to demonstrate or verbally explain procedure(s) used on site to confirm correct patient/dosage and administration to include the "seven rights".

Definition: (Seven Rights of Medication Administration)

1) Right Patient – Prepare medications one patient at a time
2) Right Drug – Check and/or have verified label of vaccine/medication is the correct vaccine/medication ordered for correct patient
3) Right Dose – Ensure dose to be given is the correct dose that was ordered
4) Right Time – Ensure vaccine/medication administration is given at the correct time
5) Right Route – Ensure drug is given via the route that is ordered
6) Right Reason – Verify correct indication for vaccine/medication use
7) Right Documentation – Ensure timely and complete documentation of vaccine/medication given to include:
   a) Date of administration
   b) Vaccine manufacturer
   c) Vaccine lot number

d) Name and title of the person who administered the vaccine and address of the facility where the permanent record will reside

e) Vaccine Information Statement (VIS)

i) Date printed on the VIS

ii) Date the VIS was given to the patient or parent/guardian

iii) CAIR2 Registry (see Links below)

Policy:

- CDC recommends that all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration policies and procedures before administering vaccines. Basic safe practices for medication/vaccine administration: (see Links below)
- Follow the seven Rights of Medication Administration and Ensure accurate documentation.

Procedure:

A. Medications must be prepared in a clean, well-lit area such as an area free of body fluids or dirty equipment such as food trays, urinals, dirty linen, and the like. You may refer to the Policy and Procedure "Infection Control" for recommended cleaning agents.

B. Do not administer any medication that contains any filthy, putrid, or decomposed substance, or if it has been prepared, packed, or held under unsanitary conditions. A drug is considered contaminated if it has been held under unsanitary conditions that may have been contaminated with filth or rendered injurious to health. Drugs that are unused are considered by the EPA to be toxic wastes and must be disposed of.

C. Have medications verified (per Scope of Practice) prior to administration
   a. See Scope of Practice for medication administration for the following: MA's and RN's (see Links below)

D. ACIP discourages the routine practice of providers' prefilling syringes.
   a. Vaccines have a similar appearance after being drawn into a syringe, prefilling may result in administration errors.
   b. Unused, provider prefilled syringes must be discarded if not used within the same day that they are filled.
   c. Unused syringes that are prefilled by the manufacturer and activated (i.e., syringe cap removed, or needle attached) should be discarded at the end of the clinic day.

E. Singe Vaccine Type
   a. In certain circumstances in which a single vaccine type is being used (e.g., in preparation for a community influenza vaccination campaign), filling a small number (10 or fewer) of syringes may be considered (5). The doses should be administered as soon as possible after filling, by the same person who filled the syringes.

Links:

https://www.cdc.gov/vaccines/hcp/admin/document-vaccines.html

http://cairweb.org/cairlogin/

https://www.rn.ca.gov/pdfs/regulations/npr-b-03.pdf

https://www.mbc.ca.gov/Licensees/Physicians_and_Surgeons/Medical_Assistants/Medical_Assistants_FAQ.aspx

First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date

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SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Vaccine Information Sheets (VIS) Protocol		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 42 USC 300aa-26(D)(2)		

Purpose:

Vaccine Immunization Statements are published by CDC is to be provided to the patient/parent/guardian prior to administration of that vaccination. Providers present a copy of the current VIS (such as a laminated copy in a binder, etc.) to the patient/parent/guardian and allow time for the patient to read and ask questions. Staff should also offer a copy each time

Definition:

Vaccine Immunization Statements are information sheets produced by the CDC that explain both the benefits and risks of a vaccine-to-vaccine recipient. The most current VIS are available from state and local health departments or can be downloaded from the CDC web site at: http://www.cdc.gov/vaccines/pubs/vis/default.htm or by calling the CDC Immunization Hotline at (800) 232-2522.

Policy:

VIS copies will be provided to patients or patient's family members in their preferred language prior to receiving a vaccination.

Procedure:

A. Health care providers must present and offer a VIS to patients prior to any vaccine. As of 2009, CDC allows providers to present a current VIS (such as a laminated copy in a binder, etc.) to the patient/parent/guardian and allow time for the patient to read and ask questions. Staff should also offer a copy each time.
B. The date the VIS was given (or presented and offered) and the publication date of the VIS must be documented in the patient's medical record.
C. Federal law allows up to 6 months for a new VIS to be used.

D. Methods for presenting and offering VIS
    - Paper Copies of the VIS can be printed and given to patients prior to vaccinations
    - Permanent, laminated office copies may be given to patients to read prior to vaccination (must offer most recent publication)
    - Patients may view VIS on a computer monitor or other video display
    - Patients may read the VIS on their phone or other digital device by downloading the pdf file from CDC's website (see Link below)
    - Patients may be given a copy of a VIS during a prior visit, or told how to access it through the internet, so they can read it in advance. These patients must still be offered a copy to read during the immunization visit as a reminder.
    - Patients must still be offered a copy of the VIS to take away following the vaccination.

E. Patient may decline the VIS
    - Document declination into the member medical record

Resources:

- The most current VIS are available from state and local health departments or can be downloaded from the CDC web site at: http://www.cdc.gov/vaccines/pubs/vis/default.htm or by calling the CDC Immunization Hotline at (800) 232-2522.
- VFC contains current VIS and provider notifications at: http://www.eziz.org/
- CDC's Facts about VIS: https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	California Immunization Registry (CAIR) Protocol		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Title 16 California Code of Regulations (CCR) Section 1746.4 (e); APL 18-004 Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Contractor shall ensure that member-specific immunization information is periodically reported to an immunization registry (is) established in the Contractor's Service Area(s) as part of the Statewide Immunization Information System.

Definition:

The California Immunization Registry (CAIR2) is a secure, confidential, statewide, computerized immunization information system for California residents.

Registry Functions:

- 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;
- track vaccine inventory–including separate tracking for VFC vaccine supplies;
- saves staff time by assisting with vaccine inventory;
- consolidates records when patients have been immunized by different providers;
- make rapid, accurate assessments of the complex vaccine schedule;
- and accurately tracks the practice's coverage rates.

Policy:

Per California Immunization Registry law (Health and Safety Code, Section 120440), all patients/parents must receive proper disclosure before patient information can be entered into and shared through CAIR. Entry into and sharing of patient information through CAIR is understood to include any and all vaccine doses or Tb test results received by the patient, regardless of when those doses or Tb tests occurred relative to the date of disclosure.

1. Patient/parents also have the right to decline to have their information in CAIR shared with other participating Organizations.
2. Organizations must use the CAIR Immunization Registry Notice to Patients and Parents ('CAIR Notice', English) (or equivalent language subject to CAIR approval) for disclosure. Translations of the 'CAIR Notice' into other languages are available on the CAIR Forms page.
3. Organizations must give a paper or laminated copy of the CAIR Notice to each patient/parent whose information will be entered into CAIR to read (patients/parents only need to be disclosed once).
4. A CAIR Notice in the patient's/parent's preferred language should be provided. The CAIR Notice is available in multiple languages on the CAIR Forms page at: http://cairweb.org/cair-forms/
5. If the patient is under the age of 18, the CAIR Notice must be given to the parent or guardian of that child.
6. A paper copy of the CAIR Notice must be given to the patient/parent to keep if requested.
7. Disclosure must take place prior to creating the patient's record in CAIR.
8. As an alternative to giving each patient/parent a copy of the CAIR Notice to read, the Organization may post CAIR Notice posters in their office waiting rooms, visible to all patients whose information may be entered into CAIR. Both English and Spanish versions of the poster must be posted. The posters should also be posted in other areas (e.g., exam rooms) to maximize the opportunity for patients/parents to read the information. The Organization must also give a paper copy of the CAIR Notice to patients/parents to keep if requested. CAIR Notice posters are available from your Local CAIR Representative.
9. The Organization should ensure that the patient/parent understands the information contained in the CAIR Notice and has the opportunity to ask questions if he/she is unclear about it.
10. Once disclosure has been performed, this must be documented in CAIR by selecting "Yes" to the question: "Has patient been disclosed (IZ/TB)?" on the CAIR Add New Patient when creating the record in CAIR screen in the patient record in CAIR. This will also default the "Has patient agreed to share?" field to "Yes". See the Sharing Policy below for further information. Organizations providing patient immunization data to CAIR through electronic data exchange should review the CAIR HL7 Data Exchange Specifications documents on the 5 Steps to Data Exchange page for instructions on incorporating disclosure and sharing information into immunization messages.
11. CAIR also receives public birth certificate records. Both the Disclosure and Share fields are automatically set to "No" in CAIR. These records cannot be opened until disclosure has been performed with the parent. Follow the on-screen instructions in CAIR for conducting disclosure and setting the Share filed for these records.

Procedure:

Organizations must give a paper or laminated copy of the CAIR Notice to each patient/parent whose information will be entered into CAIR to read (patients/parents only need to be disclosed once).

A CAIR Notice in the patient's/parent's preferred language should be provided. The CAIR Notice is available in multiple languages on the **CAIR Forms** page at: http;//cairweb.org/forms/

A reasonable mechanism must be established for patients/parents to ask questions and/or decline sharing. This should be documented in the member's medical record. Patients/parents should be referred to the CAIR Help Desk (phone: 800-578-7889, email: **CAIRHelpDesk@cdph.ca.gov**) if they have questions or concerns.

Alert:

Browser Issues: You may need to change settings or install a newer version of your browser if you are blocked from CAIR2. Information may not be displayed correctly on older versions of Firefox. Please update your browser to the latest version of Firefox to ensure all CAIR data is displayed correctly. There may be problems entering historical doses in the Chrome web browser. Try using Firefox or Internet Explorer instead.

References:

http://cairweb.org/cair-disclosure-policy/

http://cairweb.org/cair2-training-resources/

For any questions regarding these Disclosure and Share Policies, contact the CAIR Help Desk (1-800-578-7889, CAIRHelpDesk@cdph.ca.gov) or your Local CAIR Representative.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	CA State Board of Pharmacy Licensing
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	State of California Department of Consumer Affairs (DCA) The Pharmacy Law (Business and Professions Code) 4180 and 4190, Article 13 and 14
Agency//Organization Source:	DCA, DHCS
Agency/Organization URL	hhttps://www.dca.ca.gov/ https://www.dhcs.ca.gov/provgovpart/Pages/PharmacyProviderApplicationInformation.aspx

Background:

- If a pharmacy is located on site and owned by the clinic, the license issued by the CA State Board of Pharmacy must be present on site.
- Every pharmacy that dispenses a controlled substance must be registered with the DEA and be licensed by the CA State Board of Pharmacy.
- A licensed pharmacist monitors drug distribution and policies and procedures for medication dispensing and storage

Definitions:

"Dispensing" of drugs means the furnishing of drugs or devices directly to a patient or upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or upon an order to furnish drugs or transmit a prescription from a certified nurse midwife, nurse practitioner, physician assistant or pharmacist acting within the scope of his or her practice.

Purpose:

A pharmacy license is required to allow for the monitoring of drug distribution and current policies/procedures for drug storage and dispensing. (see Proper Maintenance and Storage of Drugs, Preparing and Confirming Medication/Vaccine Prior to Administration, Proper Labeling of Drugs)

Links:

Department of Consumer Affairs: Clinic License, Application: **https://www.pharmacy.ca.gov/applicants/clinic.shtml**
Clinic License Application Instructions: **https://www.pharmacy.ca.gov/forms/clinic_app_pkt.pdf**

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SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	Laboratory Test Procedures
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	42 CFR, 493.35(b)(1-3) 493.43(b)(1-3) 493.55(b)(1-3) BPC 1200-1213
Agency/Organization Source:	Centers for Medicare & Medicaid Services
Agency/Organization URL	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA

Background:

- All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease has a current, unrevoked, unsuspended site-specific Clinical Laboratory Improvement Amendment (CLIA) certificate, or evidence of renewal.
- Acceptable documentation such as the original certificate, copy of the original certificate, renewal receipt or other evidence of renewal submission is present on site or readily available upon request. The CLIA certificate or evidence of renewal should include the current site/clinic address.

Purpose:

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.

Personnel Training Standards:

- Prior to testing biological specimens, personnel have been appropriately trained for the type and complexity of the laboratory services performed.
- Personnel have demonstrated the ability to perform all testing operations reliably and to report results accurately.
- Site personnel that perform CLIA waived tests have access to and can follow test manufacturer's instructions.
- When requested, site personnel can provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.

- The required training and certification are established by legislation for personnel performing moderate and high complexity tests.

The CLIA Certificate on site includes one of the following:

1. Certificate of Waiver: Site can perform only exempt waived tests.
2. Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists, or mid-level practitioners are able to perform PPM procedures and waived tests.
3. Certificate of Registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations are determined by survey.
4. Certificate of Compliance: Lab has been surveyed and found in compliance with all applicable CLIA requirements.
5. Certificate of Accreditation: Lab is accredited by an accreditation organization approved by the Centers for Medicare & Medicaid Services (CMS).

Exceptions

1. Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
2. Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application, or
3. Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for laboratory sites within same physical location or street address.
4. A multi-site CLIA waiver can be used at all affiliated locations. A copy of the CLIA waiver must be at each individual location with the address of the main location on the waiver. A copy of the CLIA application must be reviewed by the CSR to verify the locations included for old and new locations.

Links:

CLIA Certification Application, Department of Health and Human Services Center for Medicare & Medicaid Services
https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf

Clinical Laboratory Registration Application, California Department of Public health Laboratory Services
https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/lab155.pdf

About CLIA for Family Practice, AAFP
https://www.aafp.org/practice-management/regulatory/clia.html

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Policy and Procedure

Policy Name:	Monitoring of X-ray Personnel for Radiation Exposure		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL Health and Safety Code, Division 104-Environmental Health. California Code of Regulations (CCR), Title 17, Div. 1, Chapter. 5, Subchapters 4 and 4.5. 17 CCR 30253 incorporates by reference the federal regulations specified in Title 10, Code of Federal Regulations (CFR), Part 20.		

Purpose:

The RHB of the Food, Drug, and Radiation Safety Division of CDPH enforces the Radiation Control Laws and Regulations designed to protect both the public and employees against radiation hazards. Enforcement is carried out through licensing, registration, and periodic inspection of sources of radiation, such as radiation machines.

Definition:

Acute Radiation Syndrome: Exposure to large doses of radiation over a short period of time produces a group of symptoms known as the acute radiation syndrome. These symptoms include general malaise, nausea, and vomiting, followed by a period of remission of symptoms. Later, the patient develops more severe symptoms such as fever, hemorrhage, fluid loss, anemia, and central nervous system involvement. The symptoms then gradually subside or become more severe and may lead to death.

Radiation Protection: To avoid the radiation hazards mentioned above, one must be aware of the three basic principles of time, distance, and shielding involved in protection from radiation. Obviously, the longer one stays near a source of radiation the greater will be the exposure. The same is true of proximity to the source; the closer one gets to a source of radiation the greater the exposure.

Policy:

Sensible use of protective and monitoring devices will be used to greatly reduce unnecessary exposure to radiation and allow for full realization of the many benefits of radiation.

The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA) and document procedures addressing this requirement.

Procedure:

1. Facility will post a Notice to Employees: Standards for Protection Against Radiation (https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/RHB/rhb2364.pdf)

2. All record keeping and reporting requirements are specified in regulations. Document the applicable requirements and commitments to compliance. The facility must also maintain all records of the Radiation Protection Program, including annual program audits and program content review. The following items should also be identified:
    a. The person responsible for maintaining all required records.
    b. Where the records will be maintained.
    c. The format for maintenance of records and documentation.
    d. Procedures for record keeping regarding additional authorized sites (mobile providers).

3. Facility will evaluate whether personnel monitoring for occupational exposures is required. If a facility chooses to or is required to monitor, then those who are occupationally exposed to radiation will be instructed in the following:
    a. Types of individual monitoring devices used and exchange frequency. Radiological equipment operator must use lead apron or lead shield.
    b. Use of control badges.
    c. Instructions to employees on proper use of individual monitoring devices, including consequences of deceptive exposure of the device.
    d. Procedures for ensuring that the combined occupational total effective dose equivalent (TEDE) to any employees receiving occupational exposure at your facility and at other facilities does not exceed 5 rem per year
    e. Procedures for obtaining and maintaining employees' concurrent occupational doses during that year.
    f. Procedures for ensuring that if minors are employed, their occupational TEDE does not exceed 500 millirem per year
    g. Procedures for addressing a declaration of pregnancy.
    h. Procedures for maintaining documentation of dose to the embryo/fetus and associated documentation for the declared pregnant worker.

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

Appendix A

Month / Year	Name of Employee	Protection device used	Type of Exposure	Amount of Exposure

Staff Declaration

I, _____ (to my knowledge) am not currently nor planning pregnancy.

I, _____ (to my knowledge) am not currently nor planning pregnancy.

I, _____ (to my knowledge) am not currently nor planning pregnancy.

I, _____ (to my knowledge) am not currently nor planning pregnancy.

Equipment	Date of Inspection	Inspection Report Findings

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION

CALIFORNIA RADIATION CONTROL REGULATIONS (CALIFORNIA CODE OF REGULATIONS, TITLE 17, SECTION 30255)

The California Radiation Control Regulations include standards for protection against radiation hazards. The California Department of Public Health has primary responsibility for administering these standards which apply to both employers and employees. Enforcement is carried out by the California Department of Public Health or its authorized inspection agencies.

EMPLOYEES' RESPONSIBILITIES

You should know and understand those California radiation protection standards and your employer's operating and emergency procedures which apply to your work. You should comply with these requirements for your own safety and the safety of others. Report promptly to your employer any condition which may lead to or cause a violation of these standards or employer's operating and emergency procedures.

SCOPE OF THE STANDARDS

The Standards for Protection Against Radiation define:

1. Limits on exposure to radiation and radioactive materials;
2. Actions to be taken after accidental exposure;
3. Working conditions requiring personnel monitoring, safety surveys, engineered controls, and safety equipment;
4. Proper use of caution signs, labels, and safety interlock devices;
5. Requirements for keeping worker exposure records and reporting of such exposures;
6. The requirement for specific operating and emergency procedures for radiation work; and
7. The rights of workers regarding safety inspections.

EMPLOYERS' RESPONSIBILITIES

Your employer is required to:

1. Comply with the requirements of the California Radiation Control Regulations, departmental orders, and license conditions;
2. Post or make available to you copies of the Radiation Control Regulations, any license issued thereunder, and your operating and emergency procedures;
3. Post any notice of violation of radiological working conditions; and
4. Provide you with information on your exposure to radiation.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. California Radiation Control Regulations require your employer to give you a written report if you receive an exposure greater than the limits set in the radiation safety standards. Basic limits for occupational radiation exposure can be found in section 30253 referencing title 10, Code of Federal Regulations, part 20 (10 CFR 20). Limits on exposure to radiation and exposure to concentrations of radioactive material in air are specified in 10 CFR 20, subpart C.
2. If the radiation protection standard, under 10 CFR 20 (subpart F) requires that your radiation exposure be monitored, your employer must, upon your request, give you a written report of your exposures upon termination of your employment, and make available to you the information in your dose records (as maintained under the provisions of 10 CFR 20.2106).
3. Your employer is required to provide you with an annual report of the dose you received in that monitoring year if the dose exceeds 100 millirem, or if you request an annual report.

INSPECTIONS

The Department or one of its contractors will inspect your workplace from time to time to ensure that health and safety requirements are being followed and that these requirements are effective in protecting you. Inspectors may confer privately with you at the time of inspection. At that time you may direct the inspector's attention to any condition you believe is or was a violation of the safety requirements.

In addition, if you believe at any time that any health and safety requirements are being violated, you or your workers' representative may request that an inspection be made by sending a complaint to the Department of Public Health or other official agency. Your complaint must describe the specific circumstances of the apparent violation and must be signed by you or your workers' representative. The Department is required to give your employer a copy of any such complaint. Names may be withheld at your request. You should understand, however, that the law protects you from being discharged or discriminated against in any way for filing a complaint or otherwise exercising your rights under the California Radiation Control Regulations.

POSTING REQUIREMENTS

Copies of this notice must be posted in a sufficient number of places in every establishment where employees are employed in activities regulated by the California Radiation Control Regulations, to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

FOR RADIOLOGICAL EMERGENCY ASSISTANCE (24/7), PHONE 1-800-852-7550
To contact the Radiologic Health Branch, phone (916) 327-5106
or go to the Radiologic Health Branch (https://www.cdph.ca.gov/rhb)

SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	Radiology Inspection Report and Registration
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	CCR, Title 17, Chapter 5, Division 1, Chapter 5, Subchapter 4.0, 4.5, &4.7 Health and Safety Code Sec. 114960 et seq., 106955 -107111, 114840 -114896 21 CFR 900
Agency//Organization Source:	Radiologic Health Branch
Agency/Organization URL	https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB.aspx

Background:

The Radiologic Health Branch (RHB) is within the Radiation Safety and Environmental Management Division of the Department of Public Health. RHB is responsible for providing public health functions associated with administering a radiation control program. This includes licensing of radioactive materials, registration of X-ray-producing machines, certification of medical and industrial X-ray and radioactive material users, inspection of facilities using radiation, investigation of radiation incidents, and surveillance of radioactive contamination in the environment.

Purpose:

The Radiologic Health Branch of the Food, Drug and Radiation Safety Division of the CA Department of Public Health 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.

Standard:

CDPH Radiologic Health Branch (RHB) Inspection Report will include one of the following:

1) Inspection Report and Proof of Registration, ***or***
2) Inspection Report and Proof of Registration *and* Short Form Sign-off sheet, ***or***
3) Inspection Report and Proof of Registration *and* Notice of Violation form *and* approval letter for corrective action plan from the CA RHB.

The Radiologic Inspection Report and Proof of Registration (receipt of payment or cancelled check), issued by the RHB, must be present if there is radiology equipment on site.

If any violations are found, one of two documents are issued to the site:

- "Short Form Sign-off sheet" is issued for minimal problems that are easily corrected.

- "Notice of Violation" form, requiring a site corrective action plan, is issued if there are more violations that are serious. All "Notice of Violation" corrective action plans must be accompanied by an approval letter from the CA RHB.

Resources:

- **Registration Application and Information Link:** https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB-X-ray/Registration.aspx
- For questions regarding radiologic safety (e.g. expired or no inspection letters on site), call CDPH RHB at (916) 327-5106.
- For Radiation Emergency Assistance, call 1-800-852-7550.

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Resource Guide

Subject:	Stethoscope and Sphygmomanometer Various Cuff Sizes & Blood Pressure Toolkit
Facility Site Review Source:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	AHA / AMA Target BP™
Agency//Organization Source:	San Francisco Health Plan
Agency/Organization URL	https://www.sfhp.org/providers/improving-quality/blood-pressure-toolkit/

Background:

Stethoscope and Sphygmomanometer with blood pressure cuffs, in various sizes appropriate to the population served, must be available on site.

Accurate measurement of patient's blood pressure is essential both in identifying possible cardiovascular disease risk and to improving management of high blood pressure (hypertension). Using the correct medical equipment and techniques can lead to diagnoses that are more accurate, improved treatment times, and help to maintain blood pressure goals.

Purpose:

Office will have available for primary care services a stethoscope and sphygmomanometer with various cuffs sizes and maintained according to manufacturer guidelines. (Toolkit offers information on various cuff sizes and how to measure patient for accurately sized cuff)

Staff will perform accurate blood pressure readings and to improve blood pressure measurement through training and re-training staff, validating and calibrating blood pressure devices, using appropriately sized blood pressure cuffs, standardizing blood pressure measurement practice habits – every patient, every time, and standardizing protocol for documentation of blood pressure procedure. Place poster on how to measure blood pressure appropriately in area(s) used by staff. This Blood Pressure Measurement Toolkit is available at sfhp.org.

Link: Use link or follow pathway from www.sfhp.org – Provider Resources, Improving Quality, Blood Pressure Toolkit

https://www.sfhp.org/providers/improving-quality/blood-pressure-toolkit/

Excerpt from SFHP Blood Pressure Measurement Toolkit:

Protocol for Choosing

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STEP 3

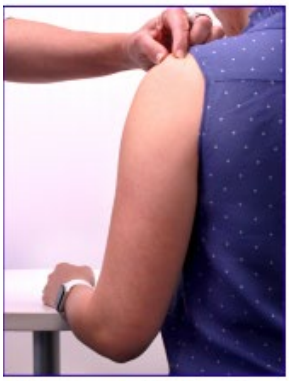
Appropriately Sized Cuffs

OBJECTIVE

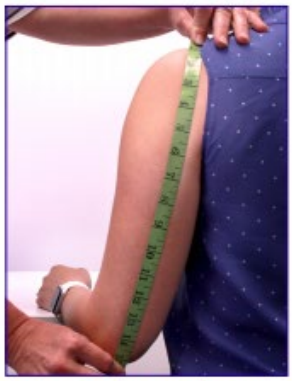
The trainee will successfully demonstrate without error the skills necessary to determine the correct cuff size for pediatric and adult patients.

Measuring Arm Circumference

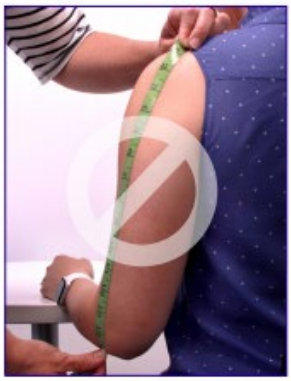
One half the distance between the acromion and the olecranon processes determines the midpoint of the arm.



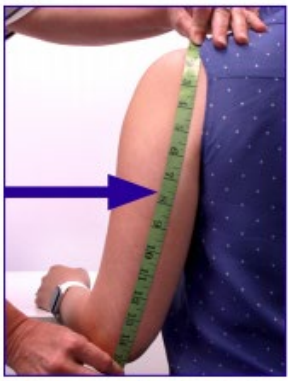
Mark spine extending from the shoulder (acromion process).



Correct tape placement for upper arm length.



Incorrect tape placement for upper arm length.



Mark upper arm length midpoint.

Measure Your Patient's Arm

The arm circumference should be printed on the inside of each cuff to eliminate confusion created by size variance among manufacturers.

ADULT

Wrap a tape measure around the patient's bicep, at mid-arm to determine the arm circumference (typically measured in cm).

PEDIATRIC

For children in whom the appropriate cuff size is difficult to determine, the mid-arm circumference (measured as the midpoint between the acromion of the scapula and olecranon of the elbow, with the shoulder in a neutral position and the elbow flexed to 90°86,95,96) should be obtained for an accurate determination of the correct cuff size.

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Policy and Procedure

Policy Name:	Health Education Materials		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL All Plan Letter (APL) 18-016, "Readability and Suitability of Written Health Education Materials"		

Purpose:

Ensure health education services are available to Plan members.

Definitions:

Health Education Services: Services may include individual instruction, group classes, family counseling and/or other health educational programs and materials provided to members by the provider, health plan, or community sponsored programs.

Policy:

Health Education Materials:

- Must be available in the appropriate threshold languages and may be located in an accessible area on site (e.g., exam room, waiting room, health education room or area), or provided to members by clinic staff and/or by Plan upon request.
- Must be available in accessible format which may include written information, audio and/or videotapes, computerized programs, and visual presentation aids for people with disabilities.
- Should include general topics for health educational material such as: Immunizations, Pregnancy, Injury Prevention, Smoking Cessation, Dental Health, Nutrition, Physical Activity, STD/HIV Prevention, Family Planning, Asthma, Hypertension, and Diabetes.
- Must meet the Medi-Cal Managed Care readability and suitability requirements for educational material distributed to Medi-Cal members.

Plan-Specific Referral Information: Plan-specific informing materials and/or resources are available on site in languages that are applicable to member population(s) primarily seen on site.

- For example, if primarily English and Spanish-speaking members are seen on site, then Plan-specific informing materials are available on site in those languages.
- Although a site may not stock informing materials in each threshold language identified for the county, site personnel has access to contact resource information for locating Plan-specific informing materials in threshold languages not typically seen on site.
- Interpreter services are provided in all identified threshold and concentration standard languages.

Note: Threshold languages are the primary languages spoken by Limited English Proficient (LEP) population groups residing in a county. A numeric threshold of 3,000 eligible LEP Medi-Cal beneficiaries or a concentration standard of 1,000 residing in a single ZIP code or 1,500 in two contiguous ZIP codes establishes the threshold languages identified by DHCS for each county.

Procedure:

Health education materials and Plan-specific resource information are:

1. Readily available on site or are made available up on request
2. Applicable to the practice and population serviced on site,
3. Available in threshold languages identified for county and/or area of site location

Reference:

- **https://www.sfhp.org/health-wellness/health-education-library/**

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

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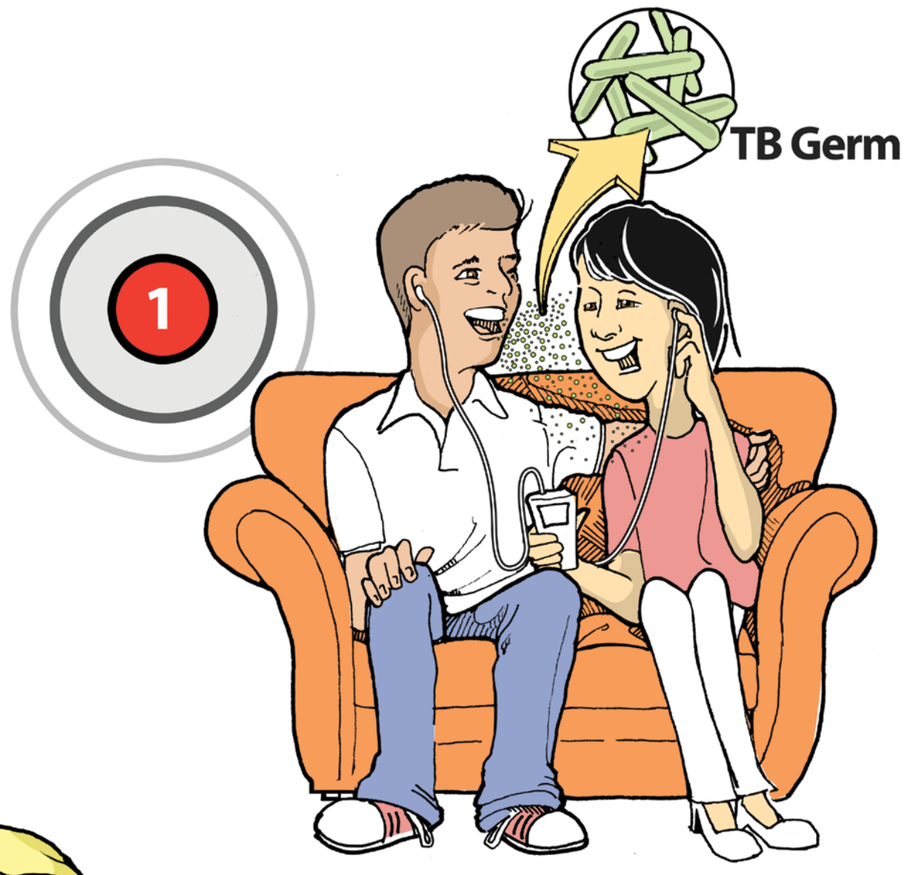
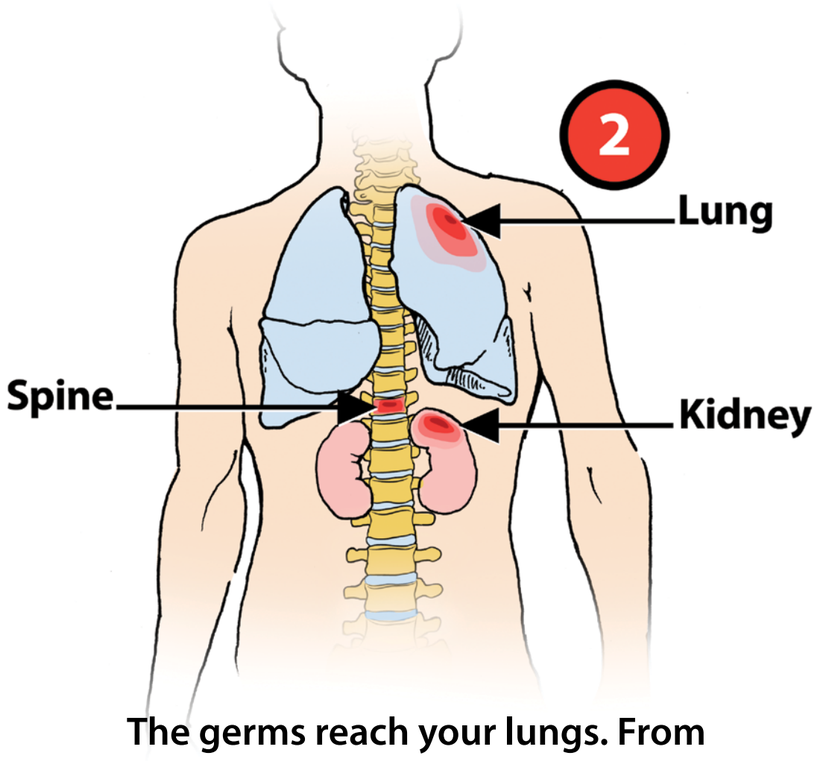


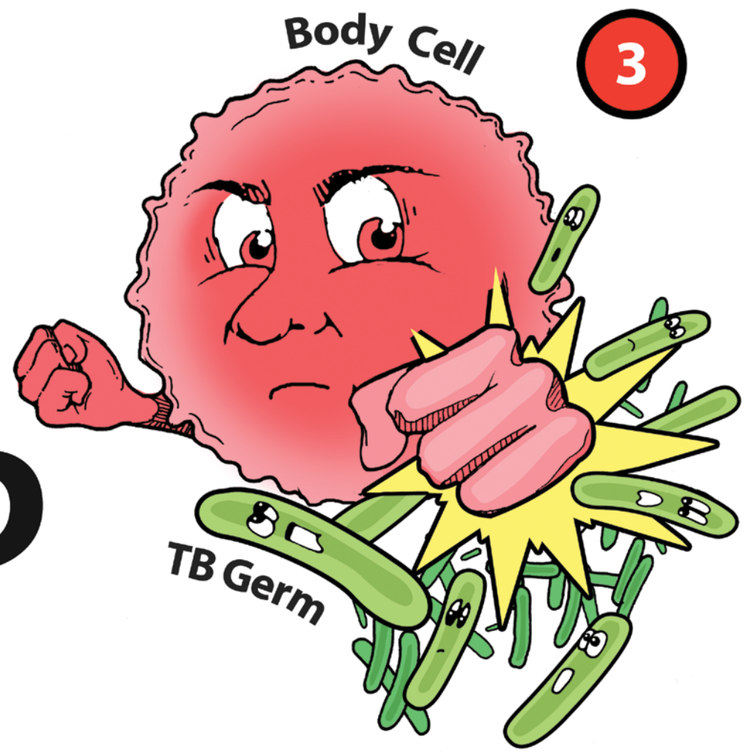
TB is spread when a person with TB disease coughs, sings, or speaks and you breathe the air contaminated with TB germs.



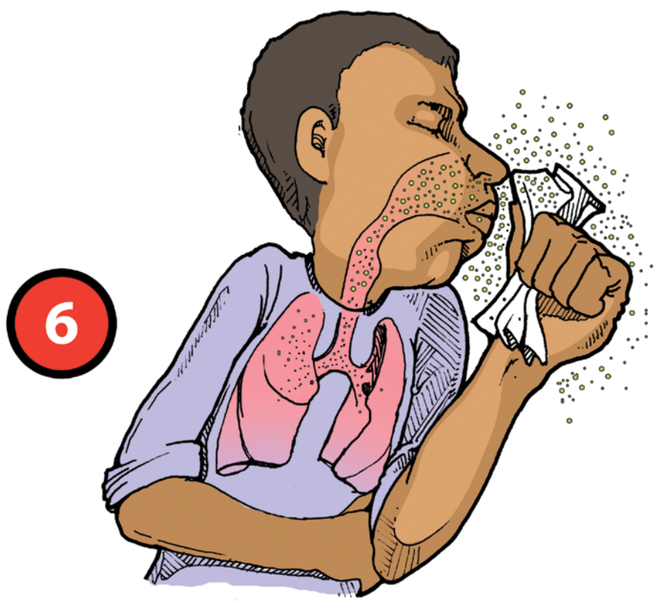
The germs reach your lungs. From there, they can go to other parts of your body.

Taking your TB medicine is very important. You need to take the medicine to help get better and to prevent the spread of TB germs to others.

STOP TB

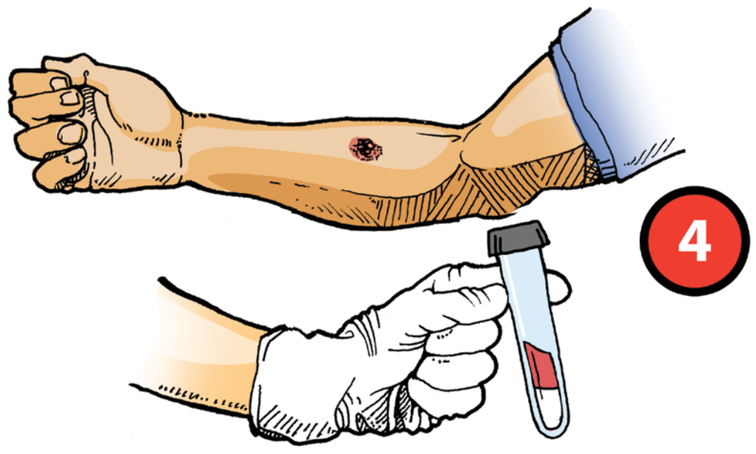


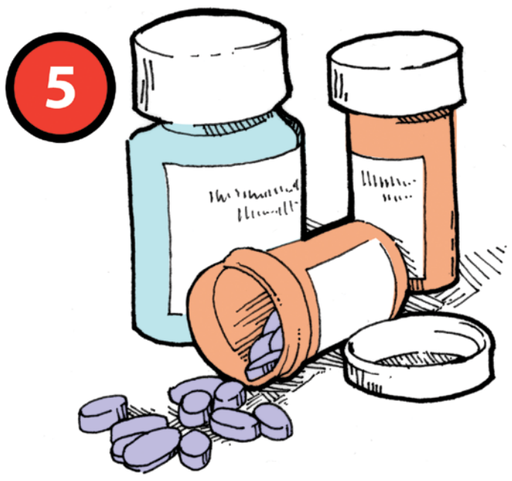
Your body fights the TB germs.



You get TB DISEASE when the TB germs multiply and attack your lungs or other parts of your body. When this happens,

- You have a positive TB skin test or TB blood test.
- You feel sick with cough, fever, weight loss, chest pain, or sweating at night.
- You have active TB germs in your body.
- You may give TB germs to others.
- You may have an abnormal chest x-ray.



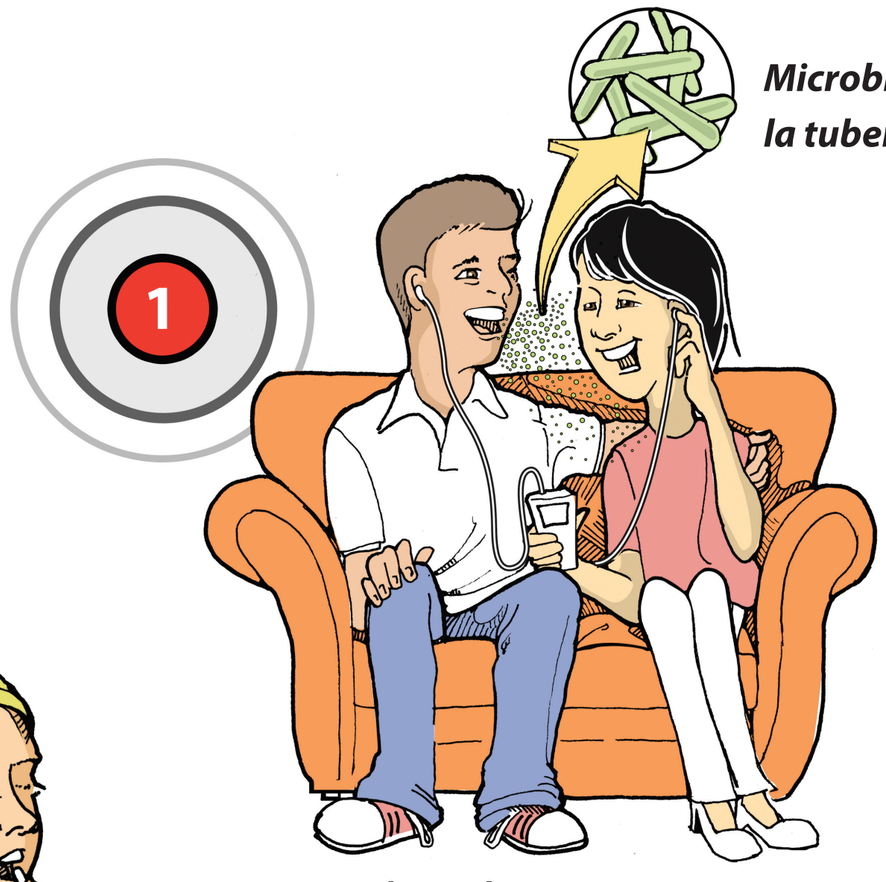


You can take medicine to treat LATENT TB INFECTION and prevent getting TB DISEASE.

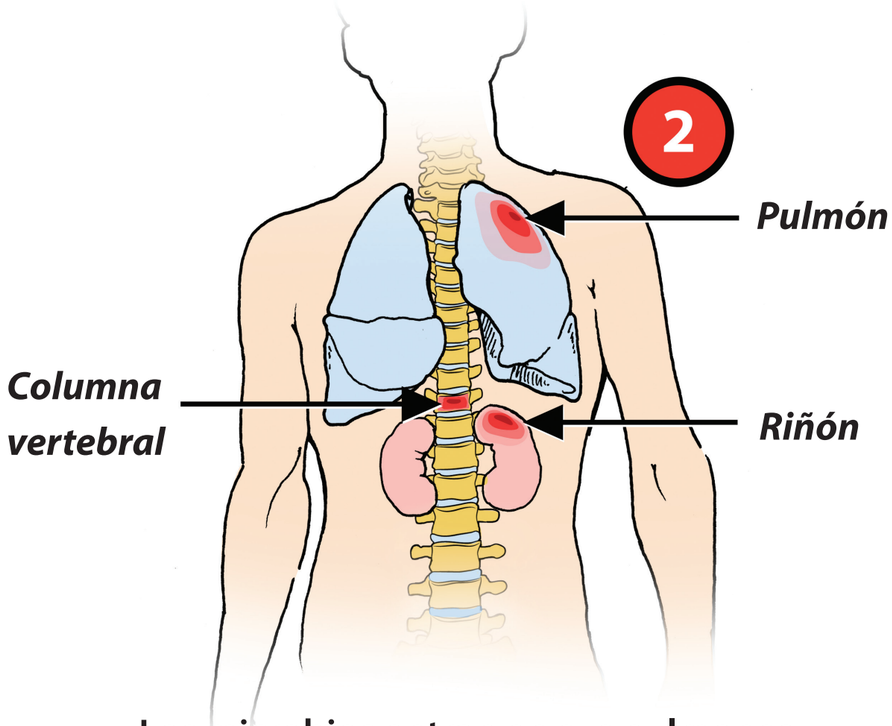
If your body controls the germs, you have LATENT TB INFECTION. When this happens,

- You may have a positive TB skin test or TB blood test.
- You don't feel sick.
- You don't have TB symptoms.
- You can't give TB germs to others.
- You have a normal chest x-ray.

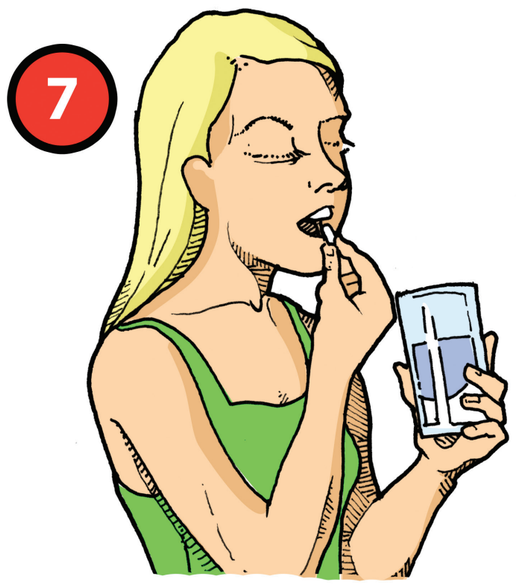
Alto a la Tuberculosis



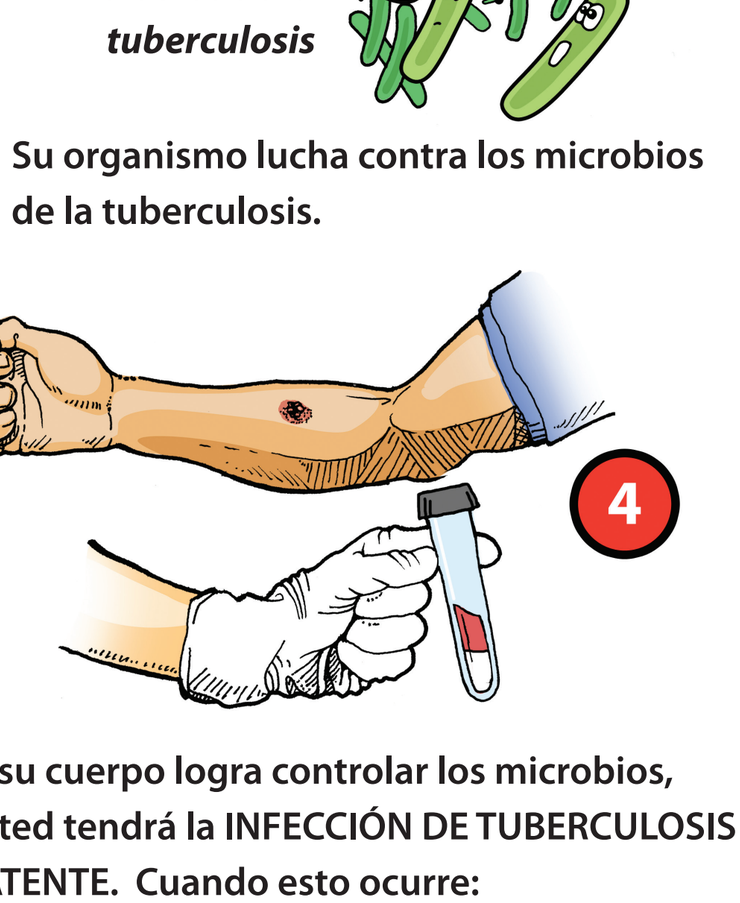
La tuberculosis se propaga cuando una persona enferma tose, canta o habla y usted respira el aire contaminado con los microbios de la tuberculosis.



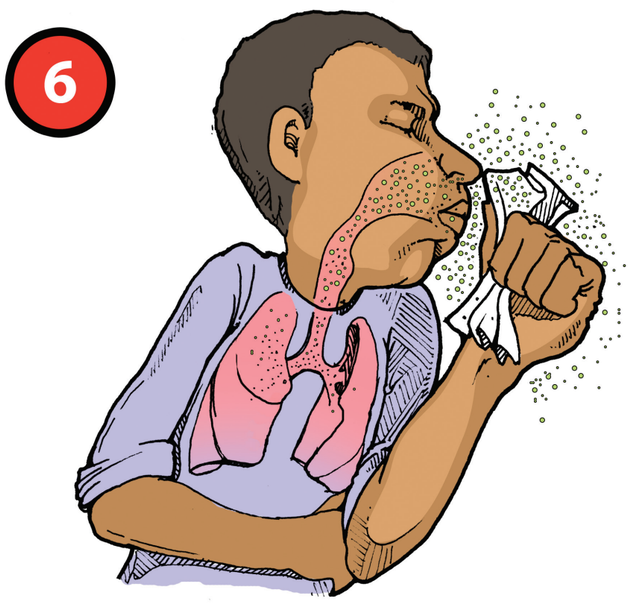
Los microbios entran en sus pulmones. De allí, pueden irse a otras partes de su cuerpo.



Tomar su medicina para la tuberculosis es muy importante. Necesita tomar la medicina para mejorarse y evitar contagiar a otras personas con los microbios de la tuberculosis.



Su organismo lucha contra los microbios de la tuberculosis.

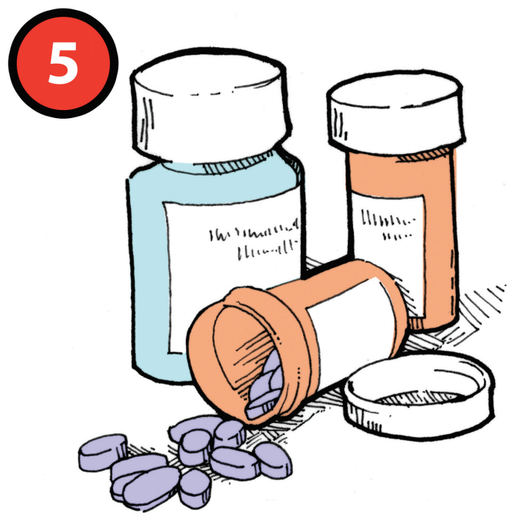


Esta enfermedad se contrae cuando los microbios de la tuberculosis se multiplican, y atacan los pulmones y otras partes del cuerpo. Cuando esto ocurre:

- Usted tiene resultados positivos a la prueba cutánea de la tuberculina o al examen de sangre para detectar la tuberculosis.
- Se siente enfermo con tos, tiene fiebre, pérdida de peso, dolor en el pecho o sudores nocturnos.
- Tiene microbios de la enfermedad de tuberculosis en su cuerpo.
- Puede pasarles los microbios de tuberculosis a otras personas.
- Puede tener una radiografía de tórax anormal.

Si su cuerpo logra controlar los microbios, usted tendrá la INFECCIÓN DE TUBERCULOSIS LATENTE. Cuando esto ocurre:

- Tiene resultados positivos a la prueba cutánea de la tuberculina o al examen de sangre para detectar la tuberculosis.
- No se siente enfermo.
- No tiene síntomas de tuberculosis.
- No puede pasarles los microbios de tuberculosis a otras personas.
- Tiene radiografía de tórax normal.



Puede tomar medicinas para el tratamiento de la INFECCIÓN DE TUBERCULOSIS LATENTE y evitar llegar a tener la ENFERMEDAD DE TUBERCULOSIS.

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
CDC

CS230017

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Blood Borne Pathogens & Waste Management		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 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.		

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:

1. **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: *Staff must know how to locate this
        A. Gloves
        B. Water repellent clothing barrier/gown
        C. Face/eye protection (e.g., goggles/face shield)
        D. 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.
2. **Blood and Other Potentially 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.

b. **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.

B. The international biohazard symbol with word "BIOHAZARD" *or* the words "Biohazardous Waste" label (fluorescent orange or red orange with contrasting lettering/symbols) is part of, or affixed to, the container.

C. Sharps containers are labeled with the words "Sharps Waste" or with the international biohazard symbol and the word "BIOHAZARD".

D. Individual containers of blood or OPIM are exempted from warning labels if placed inside a labeled secondary container for storage, transport, or disposal.

E. 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.

3. Needlestick Safety

a. Contaminated sharps are discarded immediately.

b. Sharps containers are located close to the immediate area where sharps are used and are inaccessible to unauthorized persons.

c. Sharps are not bent, removed from a syringe, or recapped. Recapping, bending, or removing contaminated needles is permissible only if there is no feasible alternative or if such actions are required for a specific medical procedure. If recapping, bending, or removal is necessary, employers must ensure that workers use either a mechanical device or a one-handed technique. Needleless systems, needles with Engineered Sharps Injury Protection (ESIP) devices, and non-needle sharps are used (incl. in emergency kits), unless exemptions have been approved by Cal/OSHA.

d. Security of portable containers in patient care areas is always maintained.

e. 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.

f. Containers are not overfilled past the manufacturer's designated fill line, or more than ¾ full.

g. Supply of containers on hand is adequate to ensure routine change-out when filled.

4. Sharps Injury Documentation

a. Site has a method in place to document sharps injuries.

b. The Sharps Injury Log must contain, at a minimum, information about the injury, the type and brand of device involved in the injury (if known), the department or work area where the exposure occurred, and an explanation of how the incident occurred.

c. The incident must be recorded in the log within 14 business days of the date the incident is reported to the employer and maintained in such a manner to protect the confidentiality of the injured employee (e.g., removal of personal identifiers) and follow-up care is documented within 14 days of injury incident.

d. Sites with 10 or fewer employees are exempt from OSHA recordkeeping requirements and are exempt from recording and maintaining a Sharps Injury Log, however, it is recommended to have a method in place to document sharps injuries regardless of the number of employees.

5. Contaminated Laundry

a. Site has a laundry service contract or a washer and dryer on site to launder contaminated laundry (soiled with blood/OPIM or containing contaminated POLICY AND PROCEDURE: Blood Borne and Waste Management Page 3 of 4 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.

6. Regulated Waste Storage

a. Regulated wastes include:

1. 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
2. Medical wastes, e.g., liquid/semi-liquid blood or OPIM, items caked with dry blood or OPIM and capable of releasing materials during handling, and contaminated sharps (Health and Safety Code, Chapter 6.1, CA Medical Waste Management Act).

b. Regulated waste is contained separately from other wastes (e.g., contaminated wastes)* and placed in red biohazardous bags with Biohazard label and stored in a closed container that is not accessible to unauthorized persons.
c. If stored outside the office, a lock secures the entry door, gate or receptacle lid, and posted warning sign(s) in English and Spanish are visible for 25-feet:

"CAUTION-BIOHAZARDOUS WASTE STORAGE AREA- UNAUTHORIZED PERSONS KEEP OUT" and
CUIDADO-ZONA DE RESIDUOUS-BIOLOGICOS PELIGOROS-PROHIBIDA LE ENTRADA A PERSONAS NO AUTHORIZADAS".

7. Medical Waste Disposal

a. Only medical waste transporters listed with CDPH can transport medical waste.
b. All medical waste transporters must carry paperwork issued by CDPH in each vehicle while transporting medical waste.
c. Medical wastes are hauled to a permitted offsite medical waste treatment facility, transfer station, or other registered generator by a registered hazardous waste transporter.
d. Limited-quantity exemption is not required for Small Quantity Generator (up to 35.2 pounds). However, a medical waste-tracking document that includes the name of the person transporting, number of waste containers (e.g., three sharps containers, or five biohazard bags), types of medical wastes, and date of transportation, is kept a minimum of 3 years for large waste generators and 2 years for small generators.

Note: Contaminated wastes include materials soiled with blood during their use but are not within the scope of regulated wastes. Contaminated waste items need not be disposed as regulated waste in labeled red bags but can be discarded as solid waste in regular trash receptacle.

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

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.

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Antiseptic Hand Cleaners
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	Infection control procedures for Standard/Universal precautions are followed.
Agency/Organization Source:	7 CFR § 3201.18 - Hand cleaners and sanitizers.
Agency/Organization URL	https://www.cdc.gov/handhygiene/

Background:

Health care antiseptics are not only used to protect the patient but also to protect the user.

Purpose:

- Soap or Antiseptic Hand Cleaner: Hand washing prevents infection transmission by removing dirt, organic material, and transient microorganisms from hands. Hand washing with plain (non-antimicrobial) soap in any form (e.g., bar, leaflet, liquid, powder, granular) is acceptable for general patient care (Association for Professionals in Infection Control and Epidemiology, Inc., 1995).

- Antimicrobial agents or alcohol-based antiseptic hand rubs are used for hand washing when indicated to remove debris and destroy transient microorganisms (e.g., before performing invasive procedures, after contact with potentially infectious materials).

- Plain and antiseptic hand wash products are properly maintained and/or dispensed to prevent contamination.

Definitions:

Hand cleaners are products formulated for personal care use in removing a variety of different soils, greases, and similar substances from human hands with or without the use of water. (7 CFR § 3201.18 - Hand cleaners and sanitizers.)

Hand sanitizers are products formulated for personal care use in removing bacteria from human hands with or without the use of water. Personal care products that are formulated for use in removing a variety of different soils, greases and similar substances and bacteria from human hands with or without the use of water are classified as hand sanitizers for the purposes of this rule. (7 CFR § 3201.18 - Hand cleaners and sanitizers.)

Standard Precautions (CDC, 1996) are used for all patients regardless of infection status. Standard precautions apply to blood, all body fluids, non-intact skin, and mucous membranes, which are treated as potentially infectious for HIV, HBV or HCV, and other bloodborne pathogens.

Universal Precautions (OSHA mandated program) implementation of work practice controls, engineering controls, bloodborne pathogen orientation/education, and record keeping in healthcare facilities.

Procedure:

- On occasions when running water is not readily available, an antiseptic hand cleanser, alcohol-based hand rub, or antiseptic towelettes is acceptable until running water is available (29 CFR 1919.1030).

- The Centers for Disease Control and Prevention (CDC) recommends that staff wash their hands often with soap and water for 20 seconds or use a hand sanitizer, especially after coughing or sneezing.

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Waste Disposal Containers
Facility Site Review Source:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	California Health and Safety Code, Sections 117600 - 118360
Agency//Organization Source:	California Department of Public Health, OSHA
Agency/Organization URL	https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/EMB/MedicalWaste/MedicalWasteManagementAct.pdf

Background:

Medical waste being held for shipment offsite for treatment must be labeled, on the lid and sides of the containers.

Biohazardous Waste Container: Regulated waste, such as I.V. tubing used to administer blood, contaminated PPE, and needles etc., must be disposed of into appropriately labeled biohazardous waste containers. [29 CFR 1910.1030(g)(1)(i)(A)]

Biohazard Label: Containers that contain regulated waste (contaminated PPE, needles, etc.) as well as refrigerators and freezers containing blood or OPIM, must bear the biohazard symbol [29 CFR 1910.1030(g)(1)(i)(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 biohazard symbol with word "BIOHAZARD" or the words "Biohazardous Waste" label (fluorescent orange or red orange with contrasting lettering/symbols) is part of, or affixed to, the container.
- Sharps containers are labeled with the words "Sharps Waste" or with the international biohazard symbol and the word "BIOHAZARD".
- Individual containers of blood or OPIM are exempted from warning labels if placed inside a labeled secondary container for storage, transport, or disposal.
- Alternative marking or color coding may be used to label contaminated laundry or specimen containers if the alternative marking permits employees on site to recognize that container requires compliance with Universal Precautions.

Purpose:

To provide guidance on appropriate labels for medical waste containers.

Resource:

Medical & Biohazard Labels may be ordered from your waste hauler, medical supply company, or purchased online (ex: Amazon.com)

https://store.stericycle.com/store/medical-accessories/medical-labels/

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Protocol for Isolating Infectious Patients		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL HSC 117600-118360, 29 CFR 1910.1030, CDC Guidelines for Isolating Precautions: Preventing Transmission of Infection Agents in Healthcare Settings, available at: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html		

Purpose:

To appropriately place patient in isolation as to prevent direct or indirect contact transmission of virulent microorganisms.

Policy:

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

Procedure:

1. If you suspect that a patient may have a communicable disease
    a. Provide patient with a face mask (if symptoms of a respiratory condition is present) and/or other personal protective equipment to reduce opportunities for transmission of microorganisms.
    b. Take the patient immediately designated isolation exam or closest available exam room, place the patient in the exam room and close the door completely.
    c. Immediately notify the physician or on-site practitioner of the situation and request that they see the patient as quickly as possible.
    d. Wipe the reception counter down with EPA-approved disinfectant cleaning solution and continue seeing patients.
2. If the practitioner indicates that the patient DOES NOT have a communicable disease, clean the room as usual between patients and continue to use the room.
3. If the practitioner indicates that the patient DOES have a communicable disease
    a. Follow the practitioner's directions and orders without variation.

b. If the practitioner indicates that the patient needs a mask, make certain that you have put on the personnel protective gown, gloves, mask, goggles from your PPE Kit (Spill Kit).
c. Assist the patient with placing the mask on correctly and escort the patient to the closest exit door preferably not through the waiting room.
d. Keep the exam room door closed when you leave.
e. Return to the room with the necessary cleaning solution and materials and equipment. Keep the room door closed while cleaning the room.
f. Be certain to dispose of all trash, exposed disposable items, etc., in a red leak proof Biohazard bag. This includes the protective gown, mask, gloves, and hair cover you are wearing while cleaning the room. Seal the bag.
g. Clean all surfaces in the room with an EPA-approved cleaning solution, do not wipe dry, and let the room air dry ensuring that the surfaces stay wet for the contact time indicated by the manufacturer on the container label.
h. Have a co-worker bring a second red bag to the room door and wearing gloves hold the bag open.
i. Place the bag from the room into the second bag, being careful not to touch your co-worker with the bag.
j. Leave exam room vacant, with door closed, for at least 1 hour before entering again.

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

List E: EPA's Registered Antimicrobial Products Effective Against Mycobacterium tuberculosis, Human HIV-1 and Hepatitis B Virus

Date: 12/02/2021

Before applying any EPA-registered disinfectant product, users must read the label to determine if the product is approved for the intended-use site or pest. This disinfectant list is not an exhaustive list of all the products that are approved for this particular pest. If you would like to review the product label information for any of these products, please visit EPA's Pesticide Product Label System. Inclusion of products in these lists does not constitute an endorsement of one product over another.

All EPA-registered pesticides must have an EPA Registration Number or Reg. No. displayed on the product label. An individual pesticide product may be marketed and sold under a variety of names. If you are seeking additional information about a pesticide product, refer to the EPA Reg. No., found on the product label, not the brand name. Alternative brand names have the same EPA Registration Number as the primary product. The EPA Reg. No. of a primary product consists of two set of numbers separated by a hyphen, for example EPA Reg. No. 12345-12. The first set of numbers refers to the company identification number, and the second set of numbers represents the product number.

In addition to primary products, distributors may also sell products with identical formulations and identical efficacy as the primary product, known as a "distributor product." Distributor products frequently use different brand names, but you can identify them by their three-part EPA Reg. No. The first two parts of the EPA Reg. No. match the primary product, plus a third set of numbers that represents the Distributor ID number. For example, EPA Reg. No. 12345-12-2567 is a distributor product with an identical formulation and efficacy to the primary product with the EPA Reg. No. 12345-12.

If you hold the primary registration for a product you believe should be added to a disinfectant list, please email the disinfectant team. In the subject line of your email include: "Include Product(s) on List [Insert list Identifier]; [Registration #(s)]." In the body, identify the Company Name, Registration Number(s), and primary brand name(s) of the product(s). Please include a copy of the label with the claims highlighted. Your request will be reviewed and the list will be revised, accordingly. EPA updates these registered disinfectant lists periodically to reflect label changes, cancellations, and transfers of product registrations. Information in the lists does not constitute a label replacement.

Questions? Please contact the pesticidequestions@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

List E: EPA's Registered Antimicrobial Products Effective Against Mycobacterium tuberculosis, Human HIV-1 and Hepatitis B Virus

Registration	Primary Brand Name	Company Name
1043-119	SPOR-KLENZ RTU	Steris Corp.
10492-4	DISCIDE ULTRA DISINFECTING	PALMERO HEALTH CARE
10492-5	DISCIDE ULTRA	PALMERO HEALTH CARE
1130-15	BURNISHINE GERMICIDAL	BURNISHINE PRODUCTS
1677-199	QUANTUM TB	ECOLAB INC
1677-226	VIRASEPT	ECOLAB INC
1677-237	OXYCIDE DAILY DISINFECTANT CLEANER	ECOLAB INC.
1839-223	SCTB WIPE	STEPAN CO
1839-83	DETERGENT	STEPAN CO
211-63	PRO-TECH DISINFECTANT	CENTRAL SOLUTIONS, INC
2915-66	SPRAY N SAN II	FULLER BRUSH COMPANY
34810-31	WEX-CIDE 128	WEXFORD LABS, Inc.
34810-35	CLEAN-CIDE READY TO	WEXFORD LABS, Inc.
3862-181	FOAMING DISINFECTANT	ABC COMPOUNDING CO., INC.
46781-12	CAVICIDE 1	METREX RESEARCH CORP
46781-13	CAVIWIPES 1	METREX RESEARCH CORP
46781-14	CAVIWIPES BLEACH	METREX RESEARCH
46781-15	CAVICIDE BLEACH	METREX RESEARCH
46781-17	CWN-07-W	METREX RESEARCH
46781-6	CAVICIDE	METREX RESEARCH CORP
46781-8	CAVIWIPES	METREX RESEARCH CORP
4959-16	ZZZ DISINFECTANT	WEST AGRO INC.
52252-7	ACTRIL COLD STERILANT	MINNTECH CORP
56392-4	CITREX HOSPITAL SPRAY	CALTECH INDUSTRIES INC
56392-7	DISPATCH HOSPITAL	CALTECH INDUSTRIES INC
5736-104	HOSPITAL DISINFECTANT	JOHNSON DIVERSEY Inc.
5741-22	STERIPHENE II BRAND	SPARTAN CHEMICAL
59894-10	KWIKKILL DISINFECYANT	M&S RESEARCH
60142-1	VIRAHOL HOSPITAL	VERIDIEN CORP
60142-3	VIRAHOL HOSPITAL SURFACE DISINFECTANT TOWELETTE	VERIDIEN CORP
67619-12	CPPC TSUNAMI	CLOROX PROFESSIONAL

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

List E: EPA's Registered Antimicrobial Products Effective Against Mycobacterium tuberculosis, Human HIV-1 and Hepatitis B Virus

Registration	Primary Brand Name	Company Name
67619-13	CPPC STORM	CLOROX PROFESSIONAL
67619-24	BLONDIE	CLOROX
67619-25	DAGWOOD	CLOROX
67619-30	GNR	CLOROX
67619-8	CPPC ULTRA BLEACH 2	CLOROX PROFESSIONAL
70060-19	ASEPTROL S10-TAB	ENGELHARDT CORP
70144-1	OPTI-CIDE 3	MICRO-SCIENTIFIC LLC
70144-2	OPTI-CIDE 3 WIPES	MICRO-SCIENTIFIC LLC
70627-2	DISINFECTANT D.C. 100	S.C. JOHNSON
70627-56	OXIVIR TB	JOHNSON DIVERSEY Inc.
70627-6	PHENOLIC DISINFECTANT HG	S.C. JOHNSON
70627-60	OXIVIR WIPES	JOHNSON DIVERSEY Inc.
70627-74	OXIVIR 1	DIVERSEY INC.
70627-77	OXIVIR 1 WIPES	DIVERSEY INC.
70791-1	ECOTRU	ENVIROSYSTEMS INC
71847-6	KLORSEPT	MEDENTECH LTD.
71847-7	KLORKLEEN 2	MEDENTECH LTD.
73232-1	ALPET D2	BEST SANITIZERS, INC
74559-1	ACCEL TB	VIROX TECHNOLOGIES INC.
74559-10	OXY-1 WIPES	VIROX TECHNOLOGIES INC.
74559-9	OXY-1 RTU	VIROX TECHNOLOGIES INC.
777-98	BRACE KITCHEN	RECKITT BENCKISER INC.
777-99	BRACE	RECKITT BENCKISER INC.
84150-3	SALSA	GOJO INDUSTRIES, INC.
84150-4	CHARLESTON	GOJO INDUSTRIES, INC.
84368-1	URTHPRO	URTHTECH
9480-10	WONDER WOMAN FORMULA B	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC
9480-12	WONDER WOMAN FORMULA B GERMICIDAL WIPES	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC
9480-14	PROJECT FLASH SPRAY	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC

List E: EPA's Registered Antimicrobial Products Effective Against Mycobacterium tuberculosis, Human HIV-1 and Hepatitis B Virus		
Registration	Primary Brand Name	Company Name
9480-4	SANI-CLOTH GERMICIDAL DISPOSABLE WIPES	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC
9480-8	PDI SANI-CLOTH BLEACH WIPES	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.
9480-9	FREESTAR	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

CHEMICAL SAFETY AND OFFICE
OF POLLUTION PREVENTION

List B: EPA's Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis

Date: 06/22/2020

Note: "An individual pesticide product may be marketed and sold under a variety of names. If you are seeking additional information about a pesticide product, refer to the EPA Registration Number, found on the product label, not the brand name. When purchasing a product for use against a specific pathogen, check the EPA Reg. No. versus the products included on this list.

All EPA-registered pesticides must have an EPA registration number. Alternative brand names have the same EPA Reg. No. as the primary product. The EPA Reg. No. of a primary product consists of two set of numbers separated by a hyphen, for example EPA Reg. No. 12345-12. The first set of numbers refers to the company identification number, and the second set of numbers represents the product number.

In addition to primary products, distributors may also sell products with identical formulations and identical efficacy as the primary products. Distributor products frequently use different brand names, but you can identify them by their three-part EPA Reg. No. The first two parts of the EPA Reg. No. match the primary product, plus a third set of numbers that represents the Distributor ID number. For example EPA Reg. No. 12345-12-2567 is a distributor product with an identical formulation and efficacy to the primary product with the EPA Reg. No. 12345-12.

Information about listed products is current as indicated by the dates on this list. If you would like to review the product label information for any of these products, please visit our product label system. Inclusion on this list does not constitute an endorsement by EPA."

If you have a product you would like added to this list please contact disinfectantslist@epa.gov.

If you have any other questions please contact pesticidequestions@epa.gov.

List B: EPA's Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis		
Registration Number	**Product Brand Name**	**Company**
1043-119	SPOR-KLENZ READY TO USE	STERIS CORPORATION
1043-120	SPOR-KLENZ CONCENTRATE	STERIS CORPORATION
1043-124	HASTE-SSD- COMPONENT B	STERIS CORPORATION
1043-125	HASTE -SSD - COMPONENT A	STERIS CORPORATION
1043-127	LpH III se Phenolic Disinfectant	STERIS CORPORATION
1043-128	Vesphene IIIse Phenolic Disinfectant	STERIS CORPORATION
1043-92	LPH SE	STERIS CORPORATION
10492-4	DISCIDE ULTRA DISINFECTING TOWELETTES	PALMERO HEALTH CARE
10492-5	DISCIDE ULTRA DISINFECTING SPRAY	PALMERO HEALTH CARE
10807-177	MISTY II DISINFECTANT & DEODORANT	AMREP, INC
1130-15	WEIMAN GERMICIDAL SOLUTION	WEIMAN PRODUCTS, LLC.
11525-30	DISINFECTANT SPRAY "G"	KIK CUSTOM PRODUCTS, INC.
1672-65	AUSTIN A-1 ULTRA DISINFECTING BLEACH	JAMES AUSTIN COMPANY
1677-129	OXONIA ACTIVE	ECOLAB INC.
1677-226	VIRASEPT	ECOLAB INC.
1677-237	FF-ATH	ECOLAB INC.
1839-174	STEPAN TOWELETTE	STEPAN COMPANY
1839-223	SCTB WIPE	STEPAN COMPANY
1839-225	SC-RTU-TB	STEPAN COMPANY
1839-83	DETERGENT DISINFECTANT PUMP SPRAY	STEPAN COMPANY
33176-5	AIRYSOL BRAND SURFACE DISINFECTANT	AMREP, INC.
33176-6	AIRYSOL BRAND MULTI-PURPOSE DISINFECTANT CLEANER	AMREP, INC.
34810-21	READY TO USE WEXCIDE	WEXFORD LABS, INC.

List B: EPA's Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis		
Registration Number	**Product Brand Name**	**Company**
34810-25	READY TO USE THYMO CIDE	WEXFORD LABS, INC.
34810-31	WEX-CIDE-128	WEXFORD LABS, INC.
34810-36	CLEAN-CIDE WIPES	WEXFORD LABS, INC.
34810-37	WEXFORD DISINFECTANT WIPES	WEXFORD LABS, INC.
3862-104	HOSPITAL SURFACE DISINFECTANT AND DEODORIZER	ABC COMPOUNDING CO, INC
3862-177	TEK-TROL DISINFECTANT CLEANER CONCENTRATE	ABC COMPOUNDING CO, INC
3862-179	OPTI-PHENE CLEANER DISINFECTANT DEODORANT	ABC COMPOUNDING CO, INC
3862-181	FOAMING DISINFECTANT CLEANER	ABC COMPOUNDING CO, INC
44446-67	CONCEPT HOSPITAL DISINFECTANT DEODORANT	QUESTVAPCO CORPORATION
46781-12	CAVICIDE 1	METREX RESEARCH
46781-13	CAVIWIPES 1	METREX RESEARCH
46781-14	CAVIWIPES BLEACH	METREX RESEARCH
46781-15	CAVICIDE BLEACH	METREX RESEARCH
46781-17	CWN-07-W	METREX RESEARCH
46781-6	CAVICIDE	METREX RESEARCH
46781-8	CAVIWIPES	METREX RESEARCH
46851-1	OMNI II	CERTOL INTERNATIONAL, LLC
46851-12	PROSPRAY WIPES, DISINFECTANT TOWELETTES	CERTOL INTERNATIONAL, LLC
46851-5	OMC II SPRAY	CERTOL INTERNATIONAL, LLC
498-134	SRAYPAK SPRAY CLEANSE	CHASE PRODUCTS CO
498-194	SPRAYPAK SPRAY DISINFECTANT/LUBR ICANT	CHASE PRODUCTS CO
52252-11	REVOX PA STERILANT	MINNTECH CORP
52252-4	MINNCARE COLD STERILANT	MINNTECH CORP
52252-7	ACTRIL COLD STERILANT	MINNTECH CORP

List B: EPA's Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis		
Registration Number	**Product Brand Name**	**Company**
54289-4	PERACLEAN 15% (PEROXYACETIC ACID SOLUTION)	EVONIK CORPORATION
56392-8	DISPATCH HOSPITAL CLEANER DISINFECTANT TOWELS WITH BLEACH	CLOROX PROFESSIONAL PRODUCTS COMPANY
5741-22	STERIPHENE II BRAND DISINFECTANT DEODORANT	SPARTAN CHEMICAL COMPANY, INC.
5813-1	CLOROX BLEACH	CLOROX CO.
5813-20	FRESH SCENT CLOROX	CLOROX CO.
5813-50	ULTRA CLOROX BRAND REGULAR BLEACH	CLOROX CO.
59894-10	KWIKKILL DISINFECTANT DEODORIZING CLEANING WIPES	M & S RESEARCH, INC.
62296-1	LET'S TOUCH	RBR PRODUCTIONS, INC.
65787-1	AMUCHINA	ALCAVIS HDC, LLC
675-1	VANI-SOL BOWL CLEANSE	RECKITT BENCKISER LLC
67603-4	SPRAY DISINFECTANT	SHERWIN- WILLIAMS DIVERSIFIED BRANDS
67619-1	CPPC BLEACH	CLOROX PROFESSIONAL PRODUCTS CO
67619-20	REX	CLOROX PROFESSIONAL PRODUCTS CO
67619-21	CARB	CLOROX PROFESSIONAL PRODUCTS CO
67619-24	BLONDIE	CLOROX PROFESSIONAL PRODUCTS CO
67619-25	DAGWOOD	CLOROX PROFESSIONAL PRODUCTS CO
67619-8	CPPC ULTRA BLEACH 2	CLOROX PROFESSIONAL PRODUCTS CO
69151-1	PAROX HOSPITAL DISINFECTANT	STERITECH, INC
70060-19	ASEPTROL S10-TAB	BASF CORPORATION
70144-1	OPTI-CIDE 3	MICRO-SCIENTIFIC LLC.
70144-2	OPTI-CIDE 3 WIPES	MICRO-SCIENTIFIC LLC
70144-4	OPTI-CIDE MAX WIPES	MICRO-SCIENTIFIC LLC.

List B: EPA's Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis		
Registration Number	**Product Brand Name**	**Company**
70144-5	OPTI-CIDE MAZ	MICRO-SCIENTIFIC LLC.
70590-1	HYPE-WIPE	CURRENT TECHNOLOGIES INC
70590-2	BLEACH-RITE DISINFECTING SPRAY WITH BLEACH	CURRENT TECHNOLOGIES INC
70627-2	DISINFECTANT D.C. 100	DIVERSEY, INC.
70627-56	OXIVIR TB	DIVERSEY, INC.
70627-6	PHENOLIC DISINFECTANT HG	DIVERSEY, INC.
70627-60	OXIVIR WIPES	DIVERSEY, INC.
70627-74	OXIVIR 1	DIVERSEY, INC.
70627-77	OXIVIR 1 WIPES	DIVERSEY, INC.
72083-2	HALOSOURCE BLEACH	HALOSOURCE, INC.
73232-1	ALPET D2	BEST SANITIZERS, INC.
74559-1	ACCEL TB	VIROX TECHNOLOGIES INC.
74559-10	OXY-1 WIPES	VIROX TECHNOLOGIES INC.
74559-3	ACCEL TB WIPES	VIROX TECHNOLOGIES INC.
74559-9	OXY-1 RTU	VIROX TECHNOLOGIES INC.
74986-5	SELECTROCIDE 5G	SELECTIVE MICRO TECHNOLOGIES, LLC
777-71	LYSOL BRAND FOAMING DISINFECTANT BASIN TUB & TILE CLEANER II	RECKITT BENCKISER LLC.
777-81	LYSOL BRAND DISINFECTANT TOILET BOWL CLEANER	RECKITT BENCKISER LLC.
777-99	BRACE	RECKITT BENCKISER LLC.
8383-12	PERIDOX	CONTEC, INC
8383-13	PERIDOX RTU (TM)	CONTEC, INC
8383-7	SPORICIDIN BRAND DISINFECTANT TOWELETTES	CONTEC, INC.
84150-3	SALSA	GOJO INDUSTRIES, INC.
84150-4	CHARLESTON	GOJO INDUSTRIES, INC.
84545-4	PERADOX HC SOLUTION PART A	SBIOMED, LLC

List B: EPA's Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis		
Registration Number	**Product Brand Name**	**Company**
84545-5	PERADOX HC ACTIVATOR SOLUTION PART B	SBIOMED, LLC
84683-1	BENEFECT BROAD SPECTRUM DISINFECTANT	OHSO CLEAN, INC.
84683-4	BENEFECT BOTANICAL DAILY CLEANER DISINFECTANT TOWELETTE	OHSO CLEAN, INC.
84683-5	CLEAN WELL BROAD SPECTRUM DISINFECTANT	OHSO CLEAN, INC.
8714-8	CLIDOX-S BASE	PHARMACAL RESEARCH LABORATORIES, INC.
87508-3	PERFORMACIDE	ODORSTAR, LLC
87742-1	THYMOX DISINFECTANT SPRAY	LABORATORIE M2
88494-1	WEDGE DISINFECTANT	NORTH AMERICAN INFECTION CONTROL, LTD.
88494-2	WEDGE DISINFECTANT WIPES	NORTH AMERICAN INFECTION CONTROL, LTD.
88494-3	PEAK DISINFECTANT	NORTH AMERICAN INFECTION CONTROL, LTD.
88494-4	PEAK DISINFECTANT WIPES	NORTH AMERICAN INFECTION CONTROL, LTD.
9150-11	CRYOCIDE 20	INTERNATIONAL DIOXCIDE INC.
9150-2	ANTHIUM DIOXCIDE	INTERNATIONAL DIOXCIDE INC.
9150-3	CARNEBON 200 2% AQUEOUS STABILIZED CHLORINE DIOXIDE	INTERNATIONAL DIOXCIDE INC.
92108-1	EXCELYTE VET	PARADIGM CONVERGENCY TECHOLOGIES CORP
9480-10	WONDER WOMAN FORMULA B	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.

List B: EPA's Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis		
Registration Number	**Product Brand Name**	**Company**
9480-12	WONDER WOMAN FORMULA B GERMICIDAL WIPES	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.
9480-14	PROJECT FLASH SPRAY	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.
9480-4	SANI-CLOTH GERMICIDAL WIPES	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.
9480-8	PDI SANI-CLOTH BLEACH WIPES	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.
9480-9	FREESTAR	PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.
954-10	CLIPPERCIDE SPRAY	KING RESEARCH, INC.
9616-13	VERTEX GERMICIDAL ULTRA BLEACH	VERTEX CHEMICAL CORP
9804-1	OXINE	BIO-CIDE INTERNATIONAL INC

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Reportable Diseases & Conditions
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	Title 17, California Code of Regulations (CCR) §2500, §2593, §2641-2643 and §2800-2812.
Agency//Organization Source:	San Francisco Department of Public Health
Agency/Organization URL	https://www.sfcdcp.org/communicable-disease/disease-reporting/

Background:

Health care providers are legally required to report certain diseases and conditions, per California Code of Regulations. The following resource includes relevant phone and fax numbers for reporting purposes, a key list of diseases and conditions and reporting timeline guide, and a Confidential Morbidity Report Form.

Purpose:

To provide health care providers with information on reportable disease and conditions to San Francisco Department of Public Health.

Resource 1:

Confidential Morbidity Report Form

Resource 2:

24/7 Disease Reporting Information for Clinicians

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.

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Personal Protective Equipment for Standard Precautions		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Personnel must be able to identify and locate Personal Protective Equipment (PPE) for Standard Precaution in the case of emergencies or to provide members with protective equipment to prevent the spread of potentially infectious materials or organisms.

Definition:

Personal protective equipment is special equipment you wear to create a barrier between you and germs. This barrier reduces the chance of touching, being exposed to, and spreading germs.

Policy:

PPE for protection against blood borne pathogen hazards is available on site and includes: 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 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.

Procedure:

I. General

A. PPE will be provided and used in the following circumstances:
- Where it has been determined that adequate engineering, and/or administrative controls do not reduce exposure potential to a safe level.
- Where development or installation of engineering controls are pending.
- Where it has been determined that PPE is necessary to protect the health and safety of employees.

- During short term, non-routine operations for which engineering controls are not practical.
- During emergency situations such as spills, ventilation malfunctions, damage control, activities, etc.

III. Employees shall:

A. Use PPE in accordance with instructions and training received.
B. Care for their personal protective equipment properly and guard against damage and contamination.
C. Report PPE malfunctions or problems to supervisory personnel.

IV. Storage of PPE

A. PPE shall be properly stored to protect against environmental conditions that might reduce the effectiveness of the equipment or result in contamination during storage. PPE having a shelf-life limitation shall be checked periodically to ensure compliance with the expiration date.
   a. The storage of PPE should be adequate to protect the PPE from contamination, loss, damage, water or sunlight.
   b. Proper storage often requires a dry and clean place that is not subject to temperature extremes

PPE	Location
Gloves	
Water repellent clothing barrier/gown	
Face/eye protection (e.g. goggles/face shield)	
Respiratory infection protection (e.g. masks)	

V. Maintenance of PPE

A. PPE, including employee-owned PPE, shall be maintained in a sanitary and serviceable condition. PPE requiring specialized servicing as specified by the manufacturer shall be serviced by qualified personnel.
B. PPE issued for exclusive use by an individual employee shall be visually inspected for defects or wear by the employee before each use. Such PPE shall be inspected frequently by the supervisor to ensure its serviceability.
C. PPE subject to use by more than one individual, such as visitor's PPE or PPE used only occasionally, shall be cleaned and disinfected by the last individual to use it, before being made available for use by subsequent personnel. Where disinfection of PPE is not applicable (i.e., thermal gloves, leather gloves, etc.), it is recommended to wash hands or use hand sanitizer before and after use.
D. PPE intended for emergency use shall be cleaned, disinfected, and placed in an operable condition after each use by the last individual to use it. Such equipment shall be inspected monthly to ensure its serviceable condition. Records shall be kept of these inspections.

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Needlestick Safety Precautions and Sharps Injury Protocol		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL H.R.5178 - Needlestick Safety and Prevention Act 8 CCR 5193, and the National Institute for Occupational Safety and Health's guidance on Preventing Needlesticks and Sharps Injuries, available at: https://www.cdc.gov/niosh/topics/bbp/sharps.html		

Purpose:

- In order to reduce or eliminate the hazards of occupational exposure, an employer must implement an exposure control plan for the worksite with details on employee protection measures. The plan must also describe how an employer will use a combination of engineering and work practice controls, ensure the use of personal protective clothing and equipment, provide training, medical surveillance, hepatitis B vaccinations, and signs and labels, among other provisions. Engineering controls are the primary means of eliminating or minimizing employee exposure and include the use of safer medical devices, such as needleless devices, shielded needle devices, and plastic capillary tubes.
- To ensure a method is in place to document sharps injuries. Needlestick injuries are a hazard for those individuals that work with "Sharps" These types of injuries can occur at any time in contact with sharps including use, medication administration, disassembly, and disposal. Sharp incidents carry increased risk for injection of hazardous drugs and contact with infectious fluids (including blood).

Definitions:

Sharps with engineered sharps injury protections

Devices that include non-needle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids, or other procedures involving the risk of sharps injury. This description covers a broad array of devices, including:

- syringes with a sliding sheath that shields the attached needle after use;
- needles that retract into a syringe after use;
- shielded or retracting catheters
- intravenous medication (IV) delivery systems that use a catheter port with a needle housed in a protective covering.

Needleless Systems

Devices which provide an alternative to needles for various procedures to reduce the risk of injury involving contaminated sharps. Examples include:

- IV medication systems which administer medication or fluids through a catheter port using non-needle connections
- Jet injection systems which deliver liquid medication beneath the skin or through a muscle.

Injuries: Needlestick injuries are wounds caused by needles or "sharps" that accidentally puncture the skin.

Policy:

1. Contaminated sharps are discarded immediately.
2. Sharps containers are located close to the immediate area where sharps are used and are inaccessible to unauthorized persons.
3. Sharps are not bent, removed from a syringe, or recapped. Recapping, bending, or removing contaminated needles is permissible only if there is no feasible alternative or if such actions are required for a specific medical procedure. If recapping, bending, or removal is necessary, employers must ensure that workers use either a mechanical device or a one-handed technique. Needleless systems, needles with Engineered Sharps Injury Protection (ESIP) devices, and non-needle sharps are used (incl. in emergency kits), unless exemptions have been approved by Cal/OSHA.
4. Security of portable containers in patient care areas is always maintained.
5. 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.
6. Containers are not overfilled past the manufacturer's designated fill line, or more than ¾ full.
7. Supply of containers on hand is adequate to ensure routine change-out when filled.

Injury Protocol

If you or a staff member experienced a needlestick or sharps injury or were exposed to the blood or other body fluid of a patient during the course of your work, immediately follow these steps:

1. Wash needlesticks and cuts with soap and water
2. Flush splashes to the nose, mouth, or skin with water
3. Irrigate eyes with clean water, saline, or sterile irrigants
4. Report the incident to your supervisor
5. Immediately seek medical treatment
6. Complete Sharps Injury Log within 14 days on which each exposure incident was reported (See Appendix A)

Reference

- https://www.govtrack.us/congress/bills/106/hr5178
- See the OSHA Needlestick Safety Frequently Asked Questions, available at: https://www.osha.gov/needlesticks/needlefaq.html
- For guidance regarding occupational exposures to HBV, HCV, and HIV and recommendations for Post-exposure Prophylaxis: https://stacks.cdc.gov/view/cdc/20711

First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date
First Name Last Name – Title	Date

Appendix A

Sharps Injury Log

The following information, if known or reasonably available, should be documented within 14 working days of the date on which each exposure incident was reported.

1. Date and time of the exposure incident: _____
2. Date of exposure incident report: _____ Report written by: _____
3. Type and brand of sharp involved: _____
4. Description of exposure incident:
    - Job Classification of exposed employee: _____
    - Department or work area where the incident occurred: _____
    - Procedure being performed by the exposed employee at the time of the accident:

      _____

      _____

      _____
    - How the incident occurred: _____
    - Body Part(s) involved: _____
    - Did the device involved have engineered sharps injury protection? Yes ____ No____
    - Was engineered sharps injury protection on the sharp involved? Yes ____ No____

If Yes	If No
A. Was the Protective mechanism activated at the time of the exposure incident? Yes No	A. Does the injured employee believe that a Protective mechanism could have prevented the injury? Yes No

B. Did the injury occur before, during, or after the mechanism was activated? _____

Comments:

_____

_____

- Does the exposed employee believe that any controls (e.g., engineering, administrative, or work practice) could have prevented the injury? Yes ___ No____

- Employee's Opinion:

_____

_____

_____

5. Comments on the exposure incident (e.g., additional relevant favors involved):

_____

_____

_____

6. Employee's interview summary:

_____

_____

_____

7. Picture(s) of the sharps(s) involved (please attach if available).

Appendix B

SHARPS INJURY LOG

MONTHY CHECK

Year:

MONTH	Injuries	Initials	**MONTH**	Injuries	Initials
January			July		
February			August		
March			September		
April			October		
May			November		
June			December		

Year:

MONTH	Injuries	Initials	**MONTH**	Injuries	Initials
January			July		
February			August		
March			September		
April			October		
May			November		
June			December		

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Routine Decontamination and Written Schedule		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 29 CFR 1910.1030 8 CCR 5193. CalOSHA's Best Practices Approach for Reducing Bloodborne Pathogen Exposure, available at: https://www.dir.ca.gov/dosh/dosh_publications/BBPBest1.pdf.		

Purpose:

To maintain a clean environment for patients and minimize the risk of patient and healthcare personnel exposure to potentially infectious microorganisms.

Contaminated work surfaces are decontaminated with an appropriate disinfectant. Written "housekeeping" schedules have been established and are followed for regular routine daily cleaning, Staff is able to identify frequently for routine cleaning of surface and equipment, the disinfectant use and responsible personnel.

Definition:

- **Contamination**: The presence of an infectious agent on a body surface; also on or in clothes, bedding, toys, surgical instruments or dressings, or other inanimate articles or substances including water, milk, and food, or that infectious agent itself.
- **Routine Decontamination**: 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 cleaning and disinfection of surfaces and equipment, the disinfectant used and responsible personnel in between patients use. Use of physical or chemical means to remove, inactivate, or destroy bloodborne or other 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.

- **Spill Procedure**: Staff is able to identify procedures for prompt decontamination of blood/body fluid spills, the disinfectant used, and the responsible person(s).
- **Disinfectant Products**: Products used for decontamination have a current EPA-approved status. Effectiveness in killing HIV/HBV/TB is stated on the manufacturer's product label. Decontamination products are used according to manufacturer's guidelines for decontamination and contact times.
- **10% Bleach Solution**: 10% bleach solution that is EPA registered, effective against TB, is changed/reconstituted ***every*** 24 hours (due to instability of bleach once mixed with water). Surface is cleaned prior to disinfecting (due to presence of organic matter (e.g., dirt, blood, excrement) inactivates active ingredient, sodium hypochlorite). Surface is air dried or allowed appropriate time (stated on label) before drying. Manufacturer's directions, *specific* to every bleach product, are followed carefully.

Note: "Contamination" means the presence or reasonably anticipated presence of blood or OPIM on any item or surface. "Decontamination" is the use of appropriate physical or chemical means to remove, inactivate or destroy bloodborne pathogens so that a surface or item is no longer capable of transmitting infectious particles and is rendered safe for handling, use or disposal.

Current EPA product lists and information is available from the EPA, Antimicrobial Division at (703) 305-1284, or at www.epa.gov/oppad001/chemregindex.htm.

Policy:

The patient care environment throughout the facility will be maintained in a state of cleanliness that meets professional standards in order to protect patients and healthcare personnel from potentially infectious microorganisms. Environmental cleaning is a team effort. Personnel responsible for cleaning the environment and equipment will receive education and training on proper environmental cleaning and disinfection methods, agent use and selection, and safety precautions.

Procedure:

Personal protective equipment (PPE) must be worn according to the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard when disposing of waste that could result in exposure to bloodborne or other potentially infectious microorganisms and hazardous material.

1. At the beginning of each day or prior to the first procedure, horizontal surfaces, procedure room lights, procedure room furniture will be damp-dusted using a clean lint free cloth dampened with a facility-approved, Environmental Protection Agency (EPA)-registered disinfectant.

2. Cleaning of procedure room between procedures must be done with a facility-approved, EPA-registered disinfectant.
    - Prepare disinfectant solution according to manufacturer's instructions.
    - Clean hands and put on gloves
    - Collect and remove waste
    - Collect and remove all soiled linen
    - Remove gloves and clean hands
    - Use a cloth dampened in disinfectant solution to clean and disinfect horizontal surfaces that have come in contact with a patient or body fluids, including blood pressure cuffs, tourniquets and leads
    - Clean suction canisters
    - Clean and disinfect bed
    - Damp mop floor in a 3 to 4 feet perimeter around the bed (larger area if contamination present); use a separate mop head per case. Allow to air dry
    - Insert new waste liner bags
    - When cleaning is complete, remove gloves and clean hands

3. Terminal cleaning of each procedure room will be completed daily when the scheduled procedures are completed for the day. Unused rooms should be cleaned once during each 24-hour period during the regularly scheduled work week because personnel entering unused rooms and moving equipment and supplies in and out of the room can increase the risk of environmental contamination. Mechanical friction and a facility approved EPA-registered agent will be used to clean the operating and procedure rooms.
    - Clean hands and put on gloves
    - Collect and remove waste
    - Collect and remove all soiled linen
    - Clean hands and change gloves
    - Clean and disinfect lights and ceiling tracks
    - Clean and disinfect all door handles, push plates, light switches and controls
    - Clean and disinfect telephones and computer keyboards
    - Spot wash all walls
    - Clean and disinfect all exterior surfaces of machines and equipment (e.g., anesthesia carts)
    - Clean and disinfect all furniture including wheels/casters
    - Clean and disinfect exterior of cabinets and doors, especially around handles
    - Clean and disinfect all horizontal surfaces
    - Clean suction canisters
    - Clean and disinfect bed
    - Clean floor making sure the bed is moved and the floor is washed underneath; move all furniture to the center of the room and continue cleaning the floor
    - Replace all furniture and equipment to its proper location
    - Damp wipe waste receptacles, dry thoroughly and re-line
    - Place a cautionary 'Wet Floor' sign at the entrance to the room
    - Remove gloves and clean hands
    - Clean and store cleaning equipment
    - Report any needed repairs

4. Other patient care areas and environmental surfaces that come in direct contact with patients will be cleaned with a facility-approved, EPA registered disinfectant.
    a. Assemble supplies
        - Ensure an adequate supply of clean cloths is available
        - Prepare fresh disinfectant solution according to manufacturer's instructions

    b. Clean hands and put on gloves

    c. Remove dirty linen, and then remove gloves and clean hands

    d. Apply clean gloves and clean room, working from clean to dirty and high to low areas of the room using fresh cloth(s) for cleaning each patient bed space and completing the cleaning of each bed space before moving to the next.
        - If a bucket is used, do not 'double-dip' cloth(s)
        - Do not shake out cloth(s)
        - Change the cleaning cloth when it is no longer saturated with disinfectant and after cleaning heavily soiled areas
        - Start by cleaning doors, door handles, push plate and touched areas of frame
        - Check walls for visible soiling and clean if required
        - Clean light switches and thermostats
        - Clean wall mounted items such as alcohol-based hand rub dispenser and glove box holder
        - Check privacy curtains for visible soiling and replace if required
        - Clean all furnishings and horizontal surfaces in the room including chairs, window sill, television, telephone, computer keypads, tables or desks. Lift items to clean the tables. Pay particular attention to high-touch surfaces
        - Wipe equipment on walls such as top of suction bottle, intercom and blood pressure manometer as well as IV pole

    e. Clean the bed

- Clean top and sides of mattress, turn over and clean underside
- Clean exposed frame
- Clean headboard, foot board, bed rails, call bell and bed controls; pay particular attention to areas that are visibly soiled and surfaces frequently touched by staff
- Clean all lower parts of bed frame, including casters
- Allow mattress to dry

f. Clean floors

g. Disposal
- Place soiled cloths in designated container for laundering or dispose
- Check sharps container and change when ¾ full (do not dust the top of a sharps container)
- Remove soiled linen if bag is full
- Place obvious waste in receptacles
- Remove waste

h. Remove gloves and clean hands; if hands are visibly soiled, wash with soap and water

i. Replenish supplies as required (e.g., gloves, ABHR, soap, paper towel)

j. Clean hands

5. Clean bathrooms, working from clean areas to dirty areas:

- Remove soiled linen from floor; wipe up any spills; remove waste
- Clean door handle and frame, light switch
- Clean wall attachments
- Clean inside and outside of sink, sink faucets and mirror; wipe plumbing under the sink; apply disinfectant to interior of sink; ensure sufficient contact time with disinfectant; rinse sink and dry fixtures
- Clean all dispensers and frames
- Clean call bell and cord
- Clean support railings, ledges/shelves
- Clean shower/tub faucets, walls and railing, scrubbing as required to remove soil; apply disinfectant to interior surfaces of shower/tub, including soap dish, faucets and shower head; ensure sufficient contact time for disinfectant; rinse and wipe dry
- Clean bedpan support, entire toilet including handle and underside of flush rim; ensure sufficient contact time with disinfectant
- Change all waste bags, clean waste can if dirty
- Remove gloves and wash hands
- Replenish paper towel, toilet paper, waste bag, soap and ABHR as required

6. Reprocessing and other sterile storage areas are to be cleaned according to the following schedule:

a. Clean all counters and floors daily

b. Clean shelves daily in sterilization, preparation, packing and decontamination areas

c. Clean shelves every three months in sterile storage areas

d. Clean case carts after every use

e. Clean walls every six months

f. Clean light fixtures, sprinkler heads and other fixtures every six months

7. Personnel responsible for cleaning must perform hand hygiene:

a. Before initial patient environment contact (e.g., before coming into the operating/procedure room or patient bed space)

b. After potential body fluid exposure (e.g., after cleaning bathroom, handling soiled linen, equipment, or waste); and

c. After patient environment contact (e.g., after cleaning patient bed space or operating/procedure room; after cleaning equipment such as stretchers; after changing mop heads).

d. Gloves must be removed on leaving each operating/procedure room or patient bed space. Personnel must **clean hands after removing gloves** as gloves do not provide complete protection against hand contamination.

References

To access the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities in its entirety, see the CDC website at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

Current EPA product lists and information is available from the EPA, Antimicrobial Division at (703) 305-1284, or at https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

FACILITY CLEANING SCHEDULE

Occurs Daily by:

Occurs Weekly by:

Solutions Used:

Includes: **MON** ☐ **TUE** ☐ **WED** ☐ **THRU** ☐ **FRI** ☐ **SAT** ☐ **SUN** ☐

Process for cleaning the following:

Floors:

Exam Tables:

Restrooms :

Furniture :

Dusting entire office:

Other:

Exam Room/Patient Restroom (if in office) & Daily Cleaning

Solution Used:

End of Day by:

After Each Patient Use by:

Biohazardous Spill during Office Hours

Assigned Person: _____

Uses only the Personnel Protection Kit (Spill or Infection control kit) Places materials in Red Biohazard bag and places in the biohazard storage container.

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Sterility of Equipment		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL 29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, and 1928.21. 29 CFR 1910.1030(d)(3)(i), 29 CFR 1910.1030(d)(3)(ii), 29 CFR 1910.1030(d)(4)(ii)(A), 29 CFR 1910.1030(d)(4)(iii)(B), 29 CFR 1910.132, 29 CFR 1910.134		

Policy:

This site will ensure that all reusable medical instruments are properly sterilized after each use.

Definitions:

- Cold/Chemical Sterilization/High Level disinfection: Product manufacturer's directions are strictly followed for instrument pre-soaking treatment, solution preparation, solution exposure procedures, safety precautions (e.g., room temperature, area ventilation), and post-sterilization processes. Sterilization exposure times and solution expiration date/time is communicated to staff. Written procedures for cold sterilization and /or high-level disinfection are available on site to staff. Centers for Disease Control and Prevention (CDC), the use of liquid chemical germicides to sterilize instruments ("cold sterilization") are limited. Sterility is not verified or assured with cold chemical sterilization and/or high-level disinfection. The first choice is always heat sterilization. The CDC refers to heat sterilization as "the method of choice when sterilizing instruments and devices. If an item is heat sensitive, it is preferable to use a heat-stable alternative or disposable item." The use of liquid chemical sterilants should be restricted to reprocessing devices that are heat-sensitive and incompatible with other sterilization methods. All other items should be heat sterilized or disposable.
- Control Methods and Work Practices to prevent or reduce exposure to the cold chemical sterilants. Cold chemical sterilants have toxic properties and are hazardous. Cold chemical sterilants must be used strictly in accordance with the manufacturer's

directions. Always consult the manufacturer for safety precautions and MSDS information. The appropriate PPE must be use to avoid inhalation or skin contact exposure to during the cold chemical sterilization/high level disinfection process.

- Control Methods and Work Practices to prevent or reduce exposure to the cold chemical sterilants. Cold chemical sterilants have toxic properties and are hazardous. Cold chemical sterilants must be used strictly in accordance with the manufacturer's directions. Always consult the manufacturer for safety precautions and MSDS information. The appropriate PPE must be use to avoid inhalation or skin contact exposure to during the cold chemical sterilization/high level disinfection process. Examples of chemicals include glutaraldehydes (Cidex), peracetic acid and hydrogen peroxide-based solutions. Glutaraldehyde is a common cold chemical sterilant. Exposure to glutaraldehyde can cause the following health effects: throat and lung irritation, breathing difficulty, nose irritation, nosebleed, burning eyes and conjunctivitis, rash, hives, headaches, and nausea. Exposure to glutaraldehyde may be prevented or reduced by using the following control methods and work practices: use local exhaust ventilation, keep glutaraldehyde baths under a fume hood where possible, avoid skin contact (use appropriate PPE-gloves and aprons made of nitrile or butyl rubber, wear goggles and face shields), use only enough sterilants to perform the required sterilization procedure, seal or cover all containers holding the sterilants, and attending training classes.
- Cold Chemical Sterilants Spillage: Staff should attend training classes in safety awareness about the use and exposure to cold chemical sterilants used on site. Staff is familiar with and is able to recognize signs and symptoms of exposure to cold chemical sterilants used on site. Staff should be aware of procedures for clean up in the event of cold chemical sterilants spills. The appropriate PPE for cold chemical sterilants clean up should be readily available.
- Autoclave/Steam Sterilization: Autoclave manufacturer's directions are strictly followed for instrument pre-cleaning, machine loading, operation safety precautions, minimum time-temperature criteria, and post sterilization processes. Written operating procedures for autoclave are available on site to staff. Documentation of sterilization loads includes: date, time and duration of run cycle, temperature, steam pressure, and operator of each run. If instruments/equipment are transported off-site for sterilization, equipment-handling and transport procedures are available on site to staff. Documentation of instruments and personnel transporting must be maintained.
- Autoclave Maintenance: Autoclave is maintained and serviced according to manufacturer's guidelines. Documentation of maintenance should include: mechanical problems, inspection dates, results/outcome of routine servicing, calibration, repairs, etc. Note: If the manufacturer's guidelines are not present on site, then the autoclave is serviced annually by a qualified technician. A dated sticker on the autoclave or a service receipt is acceptable documentation of appropriate maintenance.
- Spore Testing: Autoclave spore testing is performed at least monthly, unless otherwise stated in manufacturer's guidelines. Documentation of biological spore testing includes: date, results, types of spore test used, person performing/documenting test results. Written procedures for performing routine spore testing and for handling positive spore test results are available on site to staff. For positive spore tests, the autoclave is removed from service immediately until inspection is completed and a negative retest occurs. Procedures include: report problem, repair autoclave, retrieve all instruments sterilized since last negative spore test, re-test autoclave and re-sterilize retrieved instruments (Report/Repair/Retrieve/Retest/Re-sterilize). Biologic spore test products vary, and are designed for use based on specific autoclave type. Biologic control testing challenges the autoclave sterilization cycle with live, highly resistant, nonpathogenic spores. If spores are killed during processing, it is assumed that all other microorganisms are also killed and that the autoclave load is sterile.

Note: Documentation of monthly spore testing must be maintained onsite for sterilization performed offsite.

- Positive Mechanical, Chemical, and/or Biological Indicators: Sterilization failure can occur for reasons such as slight variation in the resistance of the spores, improper use of the sterilizer, and laboratory contamination during the culture. Sterility is not verified or assured with cold chemical sterilization. Autoclave/steam sterilization offers three methods of monitoring the sterilization process: mechanical (time, temperature, pressure in the sterilizer), chemical (internal and external indicator on the package which suggest that the sterilizer was functioning properly), and biological (spore test of device). Staff should adhere to site-specific protocol and/or manufacturer/product label for management of positive indicator (s).
- Package and Storage of sterilized items: Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination. Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer). Sterilized package labels include date of sterilization, load run identification information, and 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.
- Storage of sterilized packages: Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer). Maintenance of sterility is event related, not time related. Sterilized items are considered sterile until use, unless an event causes contamination. Sterilized items are not considered sterile if package is opened, wet/moist, discolored or damaged, and should be kept removed from sterile package storage area. Site has a process for routine evaluation of sterilized packages.

Procedure:

I. CLEANING PRIOR TO STERILIZATION

A. 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

A. 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.

III. AUTOCLAVE/STEAM STERILIZATION

A. 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 is 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, results/outcome of routine servicing, calibration, and repairs.

B. An autoclave log will be kept on file and will include the following:

- Date
- Time
- Duration of run cycle
- Temperature
- Steam pressure
- Load identification information
- Operator of each run

Monthly cleaning per manufactures recommendations. This includes the recommended cleaning solutions for the Autoclave

V. SPORE TESTING

A. Autoclave spore testing is performed at least monthly, unless otherwise stated in the manufacturer's guidelines. Spore testing reports will be maintained on file and will include the following:

- Date
- Results
- Types of spore test used
- Person performing/documenting 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 will be followed with a positive spore test:

VI. REPORT/REPAIR/RETRIEVE/RETEST/RE-STERILIZE

- Report problem to Office Manager or Doctor
- Repair autoclave
- Retrieve all instruments sterilized since last negative spore test
- Re-test autoclave
- Re-sterilize retrieved instruments

VII.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)

C. Each item in a sterile package will not be listed on the label if a master list of package contents is available elsewhere on site. It is understood that maintenance of sterility is event related, not time related. Sterilized items are considered sterile until use, unless an event causes contamination. Sterilized items are not considered sterile if package is opened, wet/moist,

discolored or damaged, and should be kept removed from sterile package storage area. This site has a process for routine evaluation of sterilized packages

References:

- 29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, and 1928.21.
- 29 CFR 1910.1030(d)(3)(i), 29 CFR 1910.1030(d)(3)(ii), 29 CFR 1910.1030(d)(4)(ii)(A), 29 CFR 1910.1030(d)(4)(iii)(B), 29 CFR 1910.132, 29 CFR 1910.134
- CDC's Guidelines on other sterilization methods, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/other-methods.html
- CDC guidelines on sterilizing heat sensitive dental instruments, available at: https://oshareview.com/2013/10/cdc-guidelines-sterilizing-heat-sensitive-dental-instruments-dental-infection-control/
- CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html
- Glutaraldehyde exposure and safety tips, refer to the CDC guidance, available at: https://www.cdc.gov/niosh/docs/2001-115/default.html
- CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf
- CDC Summary of Recommendations regarding Disinfection and Sterilization, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

_____	_____
First Name Last Name – Title	Date
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First Name Last Name – Title	Date

Autoclave Maintenance and Run Log Year _____

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Monthly Spore Testing Results												
Monthly Cleaning												
Annual Calibration												

Sterility is EVENT related, not time related; Pack is considers sterile unless an event causes contamination (example: punctured, torn, cracked packs= unsterile; evidence of water damage or yellowed packs= unsterile) Have Process to routine evaluation of sterile packs.

Log Process: Write date and Load # on Pack (if more than 1 load is run in the same day, write date and load #1 and then date and load #2 etc)

Date	Time	Load#	Item(s)	Temperature(250-254 Degrees)	Steam Pressure (15-17 psi)	Duration of Run (30 Minutes)	Person Responsible

Sterility is EVENT related, not time related; Pack is considers sterile unless an event causes contamination (example: punctured, torn, cracked packs= unsterile; evidence of water damage or yellowed packs= unsterile) Have Process to routine evaluation of sterile packs.

Log Process: Write date and Load # on Pack (if more than 1 load is run in the same day, write date and load #1 and then date and load #2 etc)

Date	Time	Load#	Item(s)	Temperature(250-254 Degrees)	Steam Pressure (15-17 psi)	Duration of Run (30 Minutes)	Person Responsible

Cold Chemical Sterilization Solution Log Sheet

Name of Solution ______________________________

Date Solution was changed	Date Solution Test Strip(according to manufacturer's directions)	Test results (+) Pass/ (-) Fail Circle one	Test By: Initials
		☐+ / -☐	
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		☐+ / -☐	
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SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Providing Meaningful Communication with Persons with Limited English Proficiency		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Facility Site Review Source:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		
Relevant Law/Standard:	Title VI of the Civil Rights Act of 1964 and Section 1557, the nondiscrimination provision of the Affordable Care Act (ACA) 22CCR Section 51309.5		

Background:

Requests for language and/or interpretation services by a non-or limited-English proficient member are documented. Member refusal of interpreter services may be documented at least once and be accepted throughout the member's care unless otherwise specified

• If bilingual staff is asked to interpret or translate, they should be qualified to do so. Assessment of ability, training on interpreter ethics and standards, and clear policies that delineate appropriate use of bilingual staff, staff or contract interpreters and translators, will help ensure quality and effective use of resources.

• Those utilizing the services of interpreters and translators should request information about certification, assessments taken, qualifications, experience, and training. Quality of interpretation should be a focus of concern for all recipients.

• Family or friends should not be used as interpreters, unless specifically requested by the member and documented in the member's chart.

• Minors (under 18 years old) accompanying member shall not be used as an interpreter.

• ACA 2010 section 1557: prohibits from using low-quality video remote interpreting services or relying on unqualified staff, translators when providing language assistance services

•Sign language interpreter services may be utilized for medically necessary health care services and related services such as obtaining medical history and health assessments, obtaining informed consents and permission for treatments, medical procedures, providing

instructions regarding medications, explaining diagnoses, treatment and prognoses of an illness, providing mental health assessment, therapy or counseling.

Purpose:

The purpose of the *Providing Meaningful Communication with Persons with Limited English Proficiency Compliance* policy is to comply with Section 1557, the civil rights provision of the Affordable Care Act of 2010 that prohibits discrimination on the grounds of race, color, national origin, sex, age, or disability in certain health programs and activities. The Section 1557 final rule applies to any health program or activity who receives Medicaid payments from the Department of Health and Human Services (HHS).

Definition:

An individual with *limited English proficiency* is a person whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English**.**

Threshold languages are the primary languages spoken by Limited English Proficient (LEP)

Policy:

_____(Facility Name) will take reasonable steps to ensure that persons with Limited English Proficiency (LEP) have meaningful access and an equal opportunity to participate in our services, activities, programs, and other benefits. The policy of _____(Facility Name) is to ensure meaningful communication with LEP patients/clients and their authorized representatives involving their medical conditions and treatment. The policy also provides for communication of information contained in vital documents, including but not limited to, waivers of rights, consent to treatment forms, financial and insurance benefit forms, etc.

All interpreters, translators and other aids needed to comply with this policy shall be provided without cost to the person being served, and patients/clients and their families will be informed of the availability of such assistance free of charge.

Language assistance will be provided through use of competent bilingual staff, staff interpreters, contracts or formal arrangements with local organizations providing interpretation or translation services, or technology and telephonic interpretation services. All staff will be provided notice of this policy and procedure, and staff that may have direct contact with LEP individuals will be trained in effective communication techniques, including the effective use of an interpreter.

_____(Facility Name) will conduct a regular review of the language access needs in all identified threshold and concentration standard languages of our patient population, as well as update and monitor the implementation of this policy and these procedures, as necessary.

_____(Facility Name) will post a notice of individuals' rights providing information about communication assistance for individuals with limited English proficiency, among other information.

Procedure:

1. IDENTIFYING LEP PERSONS AND THEIR LANGUAGE

_____(Facility Name) will promptly identify the language and communication needs of the LEP person. If necessary, staff will use a language identification card (or "I speak cards," available online at www.lep.gov) or posters to determine the language. In addition, when records are kept of past interactions with patients (clients/residents) or family members, the language used to communicate with the LEP person will be included as part of the record.

(a) Various documents can be accepted to document linguistic service needs such as Individual Health Education Behavior Assessment (IHEBA)/Staying Healthy Assessment (SHA), intake form, demographic form, Electronic Medical Record (EMR) fields, consent forms, etc.

2. OBTAINING A QUALIFIED INTEPRETER

Identify qualified staff and/or contracted agencies to provide interpretation services.

(a) Maintain an accurate and current list showing the name, language, phone number and hours of availability of bilingual staff;

Staff Name	Role	Language	Phone Number	Availability

(b) Contact the appropriate bilingual staff member to interpret, in the event that an interpreter is needed, if an employee who speaks the needed language is available and is qualified to interpret;

(c) Obtain an outside interpreter if a bilingual staff or staff interpreter is not available or does not speak the needed language.

These agencies have agreed to provide qualified interpreter services. The agency's (or agencies') telephone number(s) is/are (insert number (s)), and the hours of availability are (insert hours) are made available to staff.

Agency	Phone Number	Availability

Some LEP persons may prefer or request to use a family member or friend as an interpreter. However, family members or friends of the LEP person will not be used as interpreters unless specifically requested by that individual and **after** the LEP person has understood that an offer of an interpreter at no charge to the person has been made by the facility. Such an offer and the response will be documented in the person's file. If the LEP person chooses to use a family member or friend as an interpreter, issues of competency of interpretation, confidentiality, privacy, and conflict of interest will be considered. If the family member or friend is not competent or appropriate for any of these reasons, competent interpreter services will be provided to the LEP person.

Children and other clients/patients/residents will **not** be used to interpret, to ensure confidentiality of information and accurate communication.

3. PROVIDING WRITTEN TRANSLATIONS

(a) When translation of vital documents is needed, each unit in _____(Facility Name) will submit documents for translation into frequently encountered languages to _____(responsible staff person). Original documents being submitted for translation will be in final, approved form with updated and accurate legal and medical information.

(b) Facilities will provide translation of other written materials, if needed, as well as written notice of the availability of translation, free of charge, for LEP individuals.

(c) _____(Facility Name) will set benchmarks for translation of vital documents into additional languages over time.

4. PROVIDING NOTICE TO LEP PERSONS

_____(Facility Name) will inform LEP persons of the availability of language assistance, free of charge, by providing written notice in languages LEP persons will understand. At a minimum, notices and signs will be posted and provided in intake areas and other points of entry, including but not limited to the emergency room, outpatient areas, etc. Notification will also be provided through one or more of the following: outreach documents, telephone voice mail menus, local newspapers, radio and television stations, and/or community-based organizations.

5. MONITORING LANGUAGE NEEDS AND IMPLEMENTATION

On an ongoing basis, _____(Facility Name) will assess changes in demographics, types of services or other needs that may require reevaluation of this policy and its procedures. In addition, _____(Facility Name) will regularly assess the efficacy of these procedures, including but not limited to mechanisms for securing interpreter services, equipment used for the delivery of language assistance, complaints filed by LEP persons, feedback from patients and community organizations, etc. (include those areas applicable to your facility).

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

Resources:

Content from the Office for Civil Rights (OCR)
https://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/example-policy-procedure-persons-limited-english-proficiency/index.html

Resource 1: Preferred Language Labels

PREFERRED LANGUAGE:
Spoken:_____
Written:_____

Resource 2: Interpretation Request/Refusal Labels

Date interpreter offered:_____
Pt. Requested/Refused (circle)
Name of
Interpreter used:_____

SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	Notice of Privacy
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) 45 CFR 164.520(c)
Agency/Organization Source:	
Agency/Organization URL	

Background:

The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The right to inspect, review and receive a copy of the medical records is covered by the Privacy Rule.

Purpose:

The HIPAA Privacy Rule requires a covered health care provider with direct treatment relationships with individuals to give the notice to every individual no later than the date of first service delivery to the individual and to make a good faith effort to obtain the individual's written acknowledgment of receipt of the notice. If the provider maintains an office or other physical site where she provides health care directly to individuals, the provider must also post the notice in the facility in a clear and prominent location where individuals are likely to see it, as well as make the notice available to those who ask for a copy. See 45 CFR 164.520(c) for other notice provision requirements.

References:

Understanding Some of HIPAA's Permitted Uses and Disclosures
https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/permitted-uses/index.html

HHS offers model notices of privacy practices for both health care providers and health plans. These model notices are available for free download, in English and in Spanish, at:
http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices

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.

Clinic's Name:
Address:

Patient's Name:
Medical Record Identifier:
DOB: Gender:
Date of Service:

ACKNOWLEDGMENT OF RECEIPT OF NOTICE OF PRIVACY PRACTICES

By signing this form, you ackowledge that you received the *Notice of Privacy Practices* of the _____. The Notice tells you how we may use and disclose your protected health information. Copies of the current notice are also available on:
_____

Signature of Legal Decision Maker/Patient

Date

Print Name: (Last) (First) (MI)

Relationship to Patient

ACUSE DE RECIBO DEL AVIS DE PRACTICAS DE PRIVACIDAD

Al firmar este formularia, usted reconoce que ha recibido el Aviso de Prácticas de Privacidad del _____. El aviso l informa cómo podemos utilizar y divulgar su información médica protegida. También hay copias del aviso actual disponibles en:
_____

Firma del paciente/ la persona legalmente autorizada para tomar decisiones

Fecha

Nomber (Letra de Molde y Legible)

Parentesco con el Paciente

FOR OFFICE USE ONLY

If written acknowledgment is not obtained, please check reason:

☐ Notive of Privacy Practice Given - Legal Decision Maker Unable to Sign

☐ Notive of Privacy Practice Given - Legal Decision Maker Declined to Sign

☐ Other _____

INTERPRETER USE FOR LIMITED ENGLISH-PROFICIENT, DEAF OR HARD OF HEARING

☐ A Clinic interpreter was used. Date: _____

Signature of in-person interpreter

Print Name or ID#/Company

☐ I do not want to use a free clinic interpreter. _____ (initial)

Bilingual Individuals

Clinic Name: _____

As of (Month & Year)_____

Staff Members:

We currently have:

☐ no staff members available who are qualified to speak and/or interpret a language other than English.

☐ the following staff member(s) who are qualified to speak and/or interpret a language other than English:

Name:	
Title:	
Phone Number:	
Language(s) spoken:	
Hours of Availability:	

Name:	
Title:	
Phone Number:	
Language(s) spoken:	
Hours of Availability:	

Contractors:

The Director of Clinical Services, *(First Name, Last Name – phone number),* is responsible for maintaining a list of local bilingual interpreters/translators.

The Director of Clinical Services has chosen the following interpreter/translator to ensure that qualified persons with Limited English Proficiency (LEP) can adequately communicate with Hospice staff members.

Company/Organization:	
Contact Person:	
Address:	
Address:	
City/State/Zip:	
Voicemail:	
Fax:	
Email:	

HIPAA Notice of Privacy Practices - Sample Notice

Disclaimer: Template Notice of Privacy Practices (45 C.F.R. § 164.520)

The information provided in this document does not constitute, and is no substitute for, legal or other professional advice. Users should consult their own legal or other professional advisors for individualized guidance regarding the application of the law to their particular situations, and in connection with other compliance-related concerns.

To customize this template document, replace all of the text that is presented in brackets (i.e., "[" and "]") with text that is appropriate to your organization and circumstances. After completing the customization of this document, the document should be reviewed by an attorney who is familiar with health privacy laws and regulations in the state(s) in which the organization maintains its offices or facilities, and who is in a position to provide legal counsel to your organization.

[Note: The Notice should be completed based on the organization's actual practices, which must be documented in policies and procedures. Thus, a physician practice must have completed its policies and procedures regarding uses and disclosures, authorizations and consents, inspection and copying, accounting, alternative methods for giving information to patients, amendments, changes in the Notice and restrictions of uses and disclosures prior to finalizing this Notice.

In determining their participation in organized health care arrangements (OHCA), as set forth in Section A.3, physicians should generally list: (1) every hospital where they have staff privileges; (2) every IPA with which they participate; (3) every health plan with which they contract; and (4) any other organization that has informed the physician that the physician is an OHCA participant.

In addition, each patient right described in Section C below should be explained in enough detail so that the individual understands that each right is not absolute and is subject to some limitations and conditions. While some of these rights have been expanded to include the basic limitations provided under the law, each should be considered in light of the organization's actual practices.]

NOTICE OF PRIVACY PRACTICES

[Physician Practice Name and Address]

[Name or Title and Telephone Number of Privacy Officer]

Effective Date: [insert effective date]

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

We understand the importance of privacy and are committed to maintaining the confidentiality of your medical information. We make a record of the medical care we provide and may receive such records from others. We use these records to provide or enable other health care providers to provide quality medical care, to obtain payment for services provided to you as allowed by your health plan and to enable us to meet our professional and legal obligations to operate this medical practice properly. We are required by law to maintain the privacy of protected health information, to provide individuals with notice of our legal duties and privacy practices with respect to protected health information, and to notify affected individuals following a breach of unsecured protected health information. This notice describes how we may use and disclose your medical information. It also describes your rights and our legal obligations with respect to your medical information. If you have any questions about this Notice, please contact our Privacy Officer listed above.

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A. How This Medical Practice May Use or Disclose Your Health Information

This medical practice collects health information about you and stores it in a chart [and on a computer][and in an electronic health record/personal health record]. This is your medical record. The medical record is the property of this medical practice, but the information in the medical record belongs to you. The law permits us to use or disclose your health information for the following purposes:

1. Treatment. We use medical information about you to provide your medical care. We disclose medical information to our employees and others who are involved in providing the care you need. For example, we may share your medical information with other physicians or other health care providers who will provide services that we do not provide. Or we may share this information with a pharmacist who needs it to dispense a prescription to you, or a laboratory that performs a test. We may also disclose medical information to members of your family or others who can help you when you are sick or injured, or after you die.

2. Payment. We use and disclose medical information about you to obtain payment for the services we provide. For example, we give your health plan the information it requires before it will pay us. We may also disclose information to other health care providers to assist them in obtaining payment for services they have provided to you.

3. Health Care Operations. We may use and disclose medical information about you to operate this medical practice. For example, we may use and disclose this information to review and improve the quality of care we provide, or the competence and qualifications of our professional staff. Or we may use and disclose this information to get your health plan to authorize services or referrals. We may also use and disclose this information as necessary for medical reviews, legal services and audits, including fraud and abuse detection and compliance programs and business planning and management. We may also share your medical information with our "business associates," such as our billing service, that perform administrative services for us. We have a written contract with each of these business associates that contains terms requiring them and their subcontractors to protect the confidentiality and security of your protected health information. We may also share your information with other health care providers, health care clearinghouses or health plans that have a relationship with you, when they request this information to help them with their quality assessment and improvement activities, their patient-safety activities, their population-based efforts to improve health or reduce health care costs, their protocol development, case management or care-coordination activities, their review of competence, qualifications and performance of health care professionals, their training programs, their accreditation, certification or licensing activities, or their health care fraud and abuse detection and compliance efforts. [*Participants in organized health care arrangements only should add*: We may also share medical information about you with the other health care providers, health care clearinghouses and health plans that participate with us in "organized health care arrangements" (OHCAs) for any of the OHCAs' health care operations. OHCAs include hospitals, physician organizations, health plans, and other entities which collectively provide health care services. A listing of the OHCAs we participate in is available from the Privacy Official.]

4. [Optional]: Appointment Reminders. We may use and disclose medical information to contact and remind you about appointments. If you are not home, we may leave this information on your answering machine or in a message left with the person answering the phone.]

5. Sign In Sheet. We may use and disclose medical information about you by having you sign in when you arrive at our office. We may also call out your name when we are ready to see

you.

6. Notification and Communication With Family. We may disclose your health information to notify or assist in notifying a family member, your personal representative or another person responsible for your care about your location, your general condition or, unless you had instructed us otherwise, in the event of your death. In the event of a disaster, we may disclose information to a relief organization so that they may coordinate these notification efforts. We may also disclose information to someone who is involved with your care or helps pay for your care. If you are able and available to agree or object, we will give you the opportunity to object prior to making these disclosures, although we may disclose this information in a disaster even over your objection if we believe it is necessary to respond to the emergency circumstances. If you are unable or unavailable to agree or object, our health professionals will use their best judgment in communication with your family and others.

7. Marketing. Provided we do not receive any payment for making these communications, we may contact you to give you information about products or services related to your treatment, case management or care coordination, or to direct or recommend other treatments, therapies, health care providers or settings of care that may be of interest to you. We may similarly describe products or services provided by this practice and tell you which health plans this practice participates in. We may also encourage you to maintain a healthy lifestyle and get recommended tests, participate in a disease management program, provide you with small gifts, tell you about government sponsored health programs or encourage you to purchase a product or service when we see you, for which we may be paid. Finally, we may receive compensation which covers our cost of reminding you to take and refill your medication, or otherwise communicate about a drug or biologic that is currently prescribed for you. We will not otherwise use or disclose your medical information for marketing purposes or accept any payment for other marketing communications without your prior written authorization. The authorization will disclose whether we receive any compensation for any marketing activity you authorize, and we will stop any future marketing activity to the extent you revoke that authorization.

8. Sale of Health Information. We will not sell your health information without your prior written authorization. The authorization will disclose that we will receive compensation for your health information if you authorize us to sell it, and we will stop any future sales of your information to the extent that you revoke that authorization.

9. Required by Law. As required by law, we will use and disclose your health information, but we will limit our use or disclosure to the relevant requirements of the law. When the law requires us to report abuse, neglect or domestic violence, or respond to judicial or administrative proceedings, or to law enforcement officials, we will further comply with the requirement set forth below concerning those activities.

10. Public Health. We may, and are sometimes required by law, to disclose your health information to public health authorities for purposes related to: preventing or controlling disease, injury or disability; reporting child, elder or dependent adult abuse or neglect; reporting domestic violence; reporting to the Food and Drug Administration problems with products and reactions to medications; and reporting disease or infection exposure. When we report suspected elder or dependent adult abuse or domestic violence, we will inform you or your personal representative promptly unless in our best professional judgment, we believe the notification would place you at risk of serious harm or would require informing a

personal representative we believe is responsible for the abuse or harm.

11. Health Oversight Activities. We may, and are sometimes required by law, to disclose your health information to health oversight agencies during the course of audits, investigations, inspections, licensure and other proceedings, subject to the limitations imposed by law.

12. Judicial and Administrative Proceedings. We may, and are sometimes required by law, to disclose your health information in the course of any administrative or judicial proceeding to the extent expressly authorized by a court or administrative order. We may also disclose information about you in response to a subpoena, discovery request or other lawful process if reasonable efforts have been made to notify you of the request and you have not objected, or if your objections have been resolved by a court or administrative order.

13. Law Enforcement. We may, and are sometimes required by law, to disclose your health information to a law enforcement official for purposes such as identifying or locating a suspect, fugitive, material witness or missing person, complying with a court order, warrant, grand jury subpoena and other law enforcement purposes.

14. Coroners. We may, and are often required by law, to disclose your health information to coroners in connection with their investigations of deaths.

15. Organ or Tissue Donation. We may disclose your health information to organizations involved in procuring, banking or transplanting organs and tissues.

16. Public Safety. We may, and are sometimes required by law, to disclose your health information to appropriate persons in order to prevent or lessen a serious and imminent threat to the health or safety of a particular person or the general public.

17. Proof of Immunization. We will disclose proof of immunization to a school that is required to have it before admitting a student where you have agreed to the disclosure on behalf of yourself or your dependent.

18. Specialized Government Functions. We may disclose your health information for military or national security purposes or to correctional institutions or law enforcement officers that have you in their lawful custody.

19. Workers' Compensation. We may disclose your health information as necessary to comply with workers' compensation laws. For example, to the extent your care is covered by workers' compensation, we will make periodic reports to your employer about your condition. We are also required by law to report cases of occupational injury or occupational illness to the employer or workers' compensation insurer.

20. Change of Ownership. In the event that this medical practice is sold or merged with another organization, your health information/record will become the property of the new owner, although you will maintain the right to request that copies of your health information be transferred to another physician or medical group.

21. Breach Notification. In the case of a breach of unsecured protected health information, we will notify you as required by law. If you have provided us with a current e-mail address, we may use e-mail to communicate information related to the breach. In some circumstances our business associate may provide the notification. We may also provide notification by

other methods as appropriate. [Note: Only use e-mail notification if you are certain it will not contain PHI and it will not disclose inappropriate information. For example if your e-mail address is "digestivediseaseassociates.com" an e-mail sent with this address could, if intercepted, identify the patient and their condition.]

[Add the following three activities, or any of the three, if the organization engages or intends to engage in these activities.]

22. Psychotherapy Notes. We will not use or disclose your psychotherapy notes without your prior written authorization except for the following: 1) use by the originator of the notes for your treatment, 2) for training our staff, students and other trainees, 3) to defend ourselves if you sue us or bring some other legal proceeding, 4) if the law requires us to disclose the information to you or the Secretary of HHS or for some other reason, 5) in response to health oversight activities concerning your psychotherapist, 6) to avert a serious and imminent threat to health or safety, or 7) to the coroner or medical examiner after you die. To the extent you revoke an authorization to use or disclose your psychotherapy notes, we will stop using or disclosing these notes.

23. Research. We may disclose your health information to researchers conducting research with respect to which your written authorization is not required as approved by an Institutional Review Board or privacy board, in compliance with governing law.

24. Fundraising. We may use or disclose your demographic information in order to contact you for our fundraising activities. For example, we may use the dates that you received treatment, the department of service, your treating physician, outcome information and health insurance status to identify individuals that may be interested in participating in fundraising activities. If you do not want to receive these materials, notify the Privacy Officer listed at the top of this Notice of Privacy Practices and we will stop any further fundraising communications. Similarly, you should notify the Privacy Officer if you decide you want to start receiving these solicitations again.

B. When This Medical Practice May Not Use or Disclose Your Health Information

Except as described in this Notice of Privacy Practices, this medical practice will, consistent with its legal obligations, not use or disclose health information which identifies you without your written authorization. If you do authorize this medical practice to use or disclose your health information for another purpose, you may revoke your authorization in writing at any time.

C. Your Health Information Rights

1. Right to Request Special Privacy Protections. You have the right to request restrictions on certain uses and disclosures of your health information by a written request specifying what information you want to limit, and what limitations on our use or disclosure of that information you wish to have imposed. If you tell us not to disclose information to your commercial health plan concerning health care items or services for which you paid for in full out-of-pocket, we will abide by your request, unless we must disclose the information for treatment or legal reasons. We reserve the right to accept or reject any other request, and will notify you of our decision.

2. Right to Request Confidential Communications. You have the right to request that you receive your health information in a specific way or at a specific location. For example, you

may ask that we send information to a particular e-mail account or to your work address. We will comply with all reasonable requests submitted in writing which specify how or where you wish to receive these communications.

3. Right to Inspect and Copy. You have the right to inspect and copy your health information, with limited exceptions. To access your medical information, you must submit a written request detailing what information you want access to, whether you want to inspect it or get a copy of it, and if you want a copy, your preferred form and format. We will provide copies in your requested form and format if it is readily producible, or we will provide you with an alternative format you find acceptable, or if we can't agree and we maintain the record in an electronic format, your choice of a readable electronic or hardcopy format. We will also send a copy to any other person you designate in writing. We will charge a reasonable fee which covers our costs for labor, supplies, postage, and if requested and agreed to in advance, the cost of preparing an explanation or summary. We may deny your request under limited circumstances. If we deny your request to access your child's records or the records of an incapacitated adult you are representing because we believe allowing access would be reasonably likely to cause substantial harm to the patient, you will have a right to appeal our decision. If we deny your request to access your psychotherapy notes, you will have the right to have them transferred to another mental health professional.

4. Right to Amend or Supplement. You have a right to request that we amend your health information that you believe is incorrect or incomplete. You must make a request to amend in writing, and include the reasons you believe the information is inaccurate or incomplete. We are not required to change your health information, and will provide you with information about this medical practice's denial and how you can disagree with the denial. We may deny your request if we do not have the information, if we did not create the information (unless the person or entity that created the information is no longer available to make the amendment), if you would not be permitted to inspect or copy the information at issue, or if the information is accurate and complete as is. If we deny your request, you may submit a written statement of your disagreement with that decision, and we may, in turn, prepare a written rebuttal. All information related to any request to amend will be maintained and disclosed in conjunction with any subsequent disclosure of the disputed information.

5. Right to an Accounting of Disclosures. You have a right to receive an accounting of disclosures of your health information made by this medical practice, except that this medical practice does not have to account for the disclosures provided to you or pursuant to your written authorization, or as described in paragraphs 1 (treatment), 2 (payment), 3 (health care operations), 6 (notification and communication with family) and 18 (specialized government functions) of Section A of this Notice of Privacy Practices or disclosures for purposes of research or public health which exclude direct patient identifiers, or which are incident to a use or disclosure otherwise permitted or authorized by law, or the disclosures to a health oversight agency or law enforcement official to the extent this medical practice has received notice from that agency or official that providing this accounting would be reasonably likely to impede their activities.

6. Right to a Paper or Electronic Copy of this Notice. You have a right to notice of our legal duties and privacy practices with respect to your health information, including a right to a paper copy of this Notice of Privacy Practices, even if you have previously requested its receipt by e-mail.

If you would like to have a more detailed explanation of these rights or if you would like to

exercise one or more of these rights, contact our Privacy Officer listed at the top of this Notice of Privacy Practices.

D. Changes to this Notice of Privacy Practices

We reserve the right to amend this Notice of Privacy Practices at any time in the future. Until such amendment is made, we are required by law to comply with the terms of this Notice currently in effect. After an amendment is made, the revised Notice of Privacy Protections will apply to all protected health information that we maintain, regardless of when it was created or received. We will keep a copy of the current notice posted in our reception area, and a copy will be available at each appointment. [*For practices with websites add*: We will also post the current notice on our website.]

E. Complaints

Complaints about this Notice of Privacy Practices or how this medical practice handles your health information should be directed to our Privacy Officer listed at the top of this Notice of Privacy Practices.

If you are not satisfied with the manner in which this office handles a complaint, you may submit a formal complaint to:

[insert name and contact information for the local DHHS Office of Civil Rights]
OCRMail@hhs.gov

The complaint form may be found at **www.hhs.gov/ocr/privacy/hipaa/complaints/hipcomplaint.pdf**. You will not be penalized in any way for filing a complaint.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

Federal Coordination and Compliance Section

WHAT DOES IT MEAN TO BE A *CERTIFIED* LINGUIST?

Translation and Interpretation Procurement Series TIPS

TRUST ME, I'M A *CERTIFIED* INTERPRETER!

WHAT THIS *SHOULD* MEAN:

- Certification documentation should indicate: the certifying or assessment body (e.g., NCSC, NAJIT, FCIP, ILR), any subject area expertise (e.g., medical, conference, or court/legal), the proficiency level (e.g., master, novice, or a number score indicating proficiency), and specific language combination(s) assessed (e.g., Spanish/English).
- Interpreter scored passing marks on assessments in speaking, listening, and/or interpretation performance in the target language(s) and English.
- Interpreter maintains valid certification through continued work training, and/or continuing education credits.
- Interpreter completed a requisite number of hours interpreting.

TRUST ME, I'M A *CERTIFIED* TRANSLATOR!

WHAT THIS *SHOULD* MEAN:

- Certification documentation should indicate: the certifying or assessment body (e.g., NCSC, ATA, NAJIT, ILR), any subject area expertise (e.g., medical, conference, or court/legal), the proficiency level (e.g., master, novice, or a number score indicating proficiency), and the specific language combination(s) assessed by translation testing ***and the direction*** of translation permitted (e.g., Spanish→English, English→Spanish).
- Translator scored passing marks on assessments in reading, writing, and/or translation performance in the target language(s) and English.
- Translator maintains valid certification through continued work training, and/or continuing education credits.
- Translator demonstrated mastery of English grammar and usage in addition to grammar and usage in the target language.

BEWARE – NOT ALL CERTIFICATIONS ARE THE SAME: *IF YOU DON'T ASK*, "CERTIFIED" COULD MEAN:

- The linguist received his/her certification years earlier, and has not maintained the certification or his/her language skills.
- The linguist is a practicing interpreter and translator, but is only certified in one skill (e.g., translation, *but not* interpretation).
- The linguist is certified in one field (e.g., medical), but is *not certified* to provide language services in the required field (e.g., legal).
- The linguist is not certified, but is instead "registered," "licensed," or "qualified" by the certifying body through a less rigorous process.
- The translator is certified in only one language direction (Spanish→English), and is *not certified* to translate in the other (English→Spanish).
- The linguist received his/her certification, without training or prior experience, from an online open-book exam (or other unsuitable assessment).
- The linguist received an inadequate certification that did not assess the necessary skills (e.g., the "certified translator" was never assessed in reading)

QUESTIONS TO ASK A CERTIFIED LINGUIST:

- ☐ Are you a certified translator? Interpreter? Or both?
- ☐ What did your certification process entail?
- ☐ Which certifying authority or organization granted the certification?
- ☐ In which language(s) or language combination(s) are you certified?
- ☐ Are there any limitations to your certification?
- ☐ How much experience do you have interpreting/translating?
- ☐ Are you required to maintain your certification with experience or continuing education?

QUESTIONS TO ASK YOUR LANGUAGE SERVICES VENDOR:

- ☐ What baseline qualifications do you require your linguists to have?
- ☐ How often do you assess your linguists or vet their work?
- ☐ How do you determine whether a linguist is qualified for a job?
- ☐ Do you keep records of client complaints?
- ☐ How do you address client complaints?
- ☐ How do you verify your linguists have and maintain certification?
- ☐ What remedy do you offer clients if a linguist makes an error?
- ☐ What happens to a linguist if he/she has made substantial errors?

Federal Coordination and Compliance Section

BEFORE YOU HIRE – *ASK YOURSELF*: "WHAT ARE MY PROJECT'S LANGUAGE NEEDS?"

INTERPRETATION (ORAL)

THE PROJECT WILL REQUIRE SOMEONE WHO CAN:

- Listen to a communication in one language and orally convert it to another language (either *simultaneously* or *consecutively*) while retaining the meaning
- Orally communicate in the target language and can convey the meaning of that conversation in English (direct "in-language" communication)
- Listen to English language media and convert audio into spoken target language
- Listen to target language media and convert audio into spoken English

KEY INTERPRETATION ASSESSMENT AND CERTIFICATION BODIES:

- Federal Language Assessments Using the ILR Scale (such as the Defense Language Proficiency Test, Foreign Service Institute Test, or the FBI Language Proficiency Test)
- The Federal Court Interpreter Program (FCIP) Certification
- The American Council for the Teaching of Foreign Languages (ACTFL) and the National Association of Judiciary Interpreters and Translators (NAJIT) have certification programs
- Select state court programs (The Language Access Services Section (LASS) of the National Center for State Courts (NCSC) has drafted the testing materials used by many states) provide certifications
- Select university/college programs certify and/or assess language skills

TRANSLATION (WRITTEN)

THE PROJECT WILL REQUIRE SOMEONE WHO CAN:

- Convert written English language text into written target language
- Convert written target language text into written English
- Listen to the target language media and convert audio into written English text (transcription)
- Listen to the English language media and convert audio into written target language (transcription)
- Review target language text and orally translate meaning into spoken English (sight translation)

KEY TRANSLATION ASSESSMENT AND CERTIFICATION BODIES:

- Federal Language Assessments Using the ILR Scale (such as the Defense Language Proficiency Test, Foreign Service Institute Test, or the FBI Language Proficiency Test)
- The American Translation Association (ATA), the American Council for the Teaching of Foreign Languages (ACTFL), and the National Association of Judiciary Interpreters and Translators (NAJIT) all have certification programs
- Select state court programs (The Language Access Services Section (LASS) of the National Center for State Courts (NCSC) has drafted the testing materials used by many states) provide certifications
- Select university/college programs certify and/or assess language skills

BEWARE – LANGUAGE SERVICE DECISIONS TO AVOID:

- Hiring linguists without verifying their language qualifications
- Hiring linguists who have not had their skills independently assessed by a qualified assessment or certification body (e.g., the linguist is certified in court interpretation by the Federal Court Interpreter Program, or achieved equivalent recognition from a qualified assessment or certification body)
- Hiring a vendor or linguist without establishing a quality control plan and remedies for low quality language service
- Hiring a vendor without inquiring about the formal qualifications or certifications of its linguists
- Hiring linguists without verifying that they can meet your specific language and/or vocabulary needs (e.g., hiring a certified medical interpreter to interpret legal arguments in court)
- Hiring translators to interpret, unless they are qualified to do both
- Hiring interpreters to translate, unless they are qualified to do both
- Using self-identified multilingual staff, who are not otherwise certified or assessed in the target language, to assess the linguistic skill of a professional translator or interpreter

TIPS ON BUILDING AN EFFECTIVE STAFF LANGUAGE SERVICE PROGRAM

ARE YOU PLANNING TO USE STAFF TO PROVIDE LANGUAGE SERVICES?

KNOW YOUR LANGUAGE SERVICE NEEDS:

- ➔ Does your organization interact directly with LEP individuals?
- ➔ If so, in what capacity? In person? Online? By phone?
- ➔ What are the most common languages spoken by limited English proficient (LEP) individuals in your community? To find out, check out the Language Map App at www.lep.gov/maps

BEFORE USING MULTILINGUAL PERSONNEL:

- ➔ Do not assume that being a native speaker qualifies someone to interpret conversations or translate written documents. Interpretation, translation, and other in-language tasks often require the use of industry-specific terminology, specialized skills, and experience.
- ➔ Competency requires more than self-identification as bilingual. The most accurate way to validate language proficiency is through an independently-administered language assessment and periodic reassessment.
- ➔ Consider creating and disseminating standard policies and procedures to assess and track the language proficiency of multilingual personnel. The policy could include who has the authority to access the agency's list of multilingual personnel and who may use multilingual personnel for certain language tasks.

KNOW YOUR LANGUAGE SERVICE RESOURCES:

- ➔ Does your organization employ capable, qualified multilingual personnel?
  - → What languages do your multilingual personnel speak?
  - → What language tasks do your multilingual personnel perform?
  - → Does your organization assess the competency of multilingual personnel?
  - → Do your linguists receive additional language-skill training?
  - → Does your organization pay or provide bonuses for in-language assistance?
- ➔ Do you hire people who interpret or translate for your organization?
- ➔ How much funding is available for paying interpreters, translators, or multilingual staff?
- ➔ Do you or your staff know where to go if you need language services in an unfamiliar language?

For additional information on the certification and assessment of linguists, see our TIPS tool: What Does it Mean to be a Certified Linguist?

For information on the recruitment, hiring, retention, and assessment of linguists, continue on to the next page.

For additional copies or technical assistance in language access matters, contact the Federal Coordination and Compliance Section at LEP@usdoj.gov

Recruiting, Hiring, and Retaining Multilingual Personnel:

In the process of recruiting, hiring, compensating, and retaining qualified multilingual personnel, consider the following:

Recruiting Multilingual Personnel:

- ➔ Could your organization reach out to local language communities in order to solicit suggestions for hiring qualified speakers of that language?
- ➔ Are there recruitment sources and networks your organization can work with to promote your hiring needs and attract qualified linguists?

Hiring and Retaining Multilingual Personnel:

- ➔ Will language proficiency be a requirement or just an ability that would make an applicant more appealing? Does the job analysis support language proficiency and will it be documented in the position description?
- ➔ Will in-house language tasks be part of an employee's performance plan or are they collateral duties?
- ➔ Will staff linguists receive pay differentials, workload adjustments, or other incentives intended to recruit and retain multilingual personnel?
- ➔ A multilingual employee hired for a non-language specific task (e.g., accountant) may be inundated with requests for language assistance. How will management ensure the employee's personal career growth while continuing to be responsive to in-house language requests?
- ➔ Could you exchange, share, and review sample job descriptions with others in your industry to maintain consistency regarding language proficiency skills?
- ➔ Could labor unions or other bargaining units affect your agency's decision to recruit, hire, assess, or retain multilingual employees?

The ILR Scale is a metric for measuring an individual's language proficiency. There is no "ILR test," but several agencies and private organizations have adapted the ILR Scale's skill level descriptions into a proficiency test.

How Do I Assess the Language Skills of My Multilingual Personnel:?

To ensure effective communication between multilingual employees and LEP persons, agencies should assess the oral and/or written proficiencies of multilingual employees. There are many forms of assessment, and many considerations such as time, cost, efficiency, accuracy, and consistency.

Structured Testing and Assessment:

Effective testing and assessment often involves either (1) an independently administered test, or (2) a structured in-language interview conducted by a linguist qualified to assess language proficiency.

Independent verification is the most accurate way to determine whether a linguist is proficient. Independent assessments also tend to be quite rigorous, independently testing and scoring individual language skills such as reading, speaking, listening, writing, interpreting, and translating. The federal government uses the Interagency Language Roundtable scale as its metric for measuring language skill and proficiency (see, www.govtilr.org).

Periodically reassess your multilingual employees because, if not used, language skills may erode over time.

Unverifiable Assessment:

Occasionally, organizations employ other methods to verify linguistic qualifications, for example reviewing translated work samples, administering a self-assessment language questionnaire, or reviewing educational linguistic background or credentials.

It is important to note that these methods may not provide an organization with an independent or verifiable baseline of an employee's language skill.

Appropriate Use of Medical Interpreters

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More than 25 million Americans speak English "less than very well," according to the U.S. Census Bureau. This population is less able to access health care and is at higher risk of adverse outcomes such as drug complications and decreased patient satisfaction. Title VI of the Civil Rights Act mandates that interpreter services be provided for patients with limited English proficiency who need this service, despite the lack of reimbursement in most states. Professional interpreters are superior to the usual practice of using ad hoc interpreters (i.e., family, friends, or untrained staff). Untrained interpreters are more likely to make errors, violate confidentiality, and increase the risk of poor outcomes. Children should never be used as interpreters except in emergencies. When using an interpreter, the clinician should address the patient directly and seat the interpreter next to or slightly behind the patient. Statements should be short, and the discussion should be limited to three major points. In addition to acting as a conduit for the discussion, the interpreter may serve as a cultural liaison between the physician and patient. When a bilingual clinician or a professional interpreter is not available, phone interpretation services or trained bilingual staff members are reasonable alternatives. The use of professional interpreters (in person or via telephone) increases patient satisfaction, improves adherence and outcomes, and reduces adverse events, thus limiting malpractice risk. (*Am Fam Physician*. 2014;90(7):476-480. Copyright © 2014 American Academy of Family Physicians.)

CME This clinical content conforms to AAFP criteria for continuing medical education (CME). See CME Quiz Questions on page 447.

Author disclosure: No relevant financial affiliations.

More than 25 million Americans speak English "less than very well," according to the U.S. Census Bureau, and more than 60 million speak a language other than English at home.[1] This population is the least likely to receive preventive care, have access to regular care, or be satisfied with their care.[2] Patients with limited English proficiency are much more likely to have adverse effects from drug complications, poor understanding of diagnoses, low health literacy, and a greater risk of being misunderstood by their physicians.[3,4]

Title VI of the Civil Rights Act requires interpreter services for all patients with limited English proficiency who are receiving federal financial assistance, with the exception of Medicare Part B.[5] Failure to provide these services when necessary is considered discriminatory and illegal. In most states, however, these services are an unfunded mandate because Medicaid, Medicare, and most private insurers do not pay for interpreter services,[5] although a prolonged service fee may be appropriate because of the extra time required for office visits.[6] The American Academy of Family Physicians supports legislation to improve health care access and provide funding for patients with limited English proficiency and those who are deaf,[7] but because professional interpreter services are not reimbursable, many clinicians still rely on family, friends, or bilingual staff as ad hoc interpreters, which increases the risk of patient dissatisfaction, medical errors, unnecessary testing, poor adherence, and malpractice exposure.[5,8] In one example, office staff misinterpreted the word intoxicado as intoxicated instead of the intended meaning of inadvertent toxicity. A fruitless evaluation for drug abuse was conducted while an intracerebral hemorrhage was missed, resulting in a $71 million malpractice award.[9]

Professional medical interpreters are trained to interpret the spoken word, whereas translators work with written words. Although the two professions are often confused, they require different skill sets, with interpreters working in live situations.[10] National certification for medical interpreters is still fairly new and is provided by the Certification Commission for Healthcare Interpreters (http://www.cchicertification.org) or the National Board of Certification for Medical Interpreters (http://www.certifiedmedicalinterpreters.org). The Registry of Interpreters for the Deaf provides certification for deaf interpretation (http://www.rid.org).

SORT: KEY RECOMMENDATIONS FOR PRACTICE

Clinical recommendation	*Evidence rating*	*References*
Use of a trained interpreter meets the legal requirements of Title VI of the Civil Rights Act and should be offered to patients with limited English proficiency.	C	5, 15, 24
When using an interpreter, the clinician should address the patient directly in the first person.	C	10
Seating the interpreter next to or slightly behind the patient facilitates better communication.	C	10, 13
When using an interpreter, the clinician should allow for sentence-by-sentence interpretation.	C	6
A trained interpreter should be used to improve communication (resulting in fewer errors), clinical outcomes, and satisfaction with care in patients with limited English proficiency.	B	4, 8, 17, 23

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to http://www.aafp.org/afpsort.

Choosing an Interpreter

Professional interpreters are often not available, although larger institutions and universities employ them or use employee or community language banks as needed. Therefore, multilingual staff members should be encouraged to receive additional training in interpretation technique; fluency alone does not make them effective interpreters. With more than 100 languages spoken in the United States,[4] the most feasible option for most offices is usually a telephone service such as LanguageLine Solutions (http://languageline.com) or CyraCom Language Solutions (http://www.cyracom.com). Soon after a request, an on-call trained interpreter is connected by phone for the interview. Clinics can subscribe to the service or pay per call ($2 to $3 per minute without a contract). Use of telephone interpreters is not inferior to having a bilingual health care professional.[11] However, if a patient insists on having a family member as an interpreter, this should be recorded in the patient's chart.[6]

Interpreter services for patients who are deaf are usually provided through video remote interpreting, in which a two-way video link facilitates American sign language communication. Video relays (on-screen sign language interpreters), closed captioning (spoken words appearing on screen), telephone typewriters, lip reading, and simple texting or writing are alternative means of communication. It is not advisable to rely on computerized translation services in which typed phrases are automatically translated online or spoken with a prerecorded voice. These are often rough renderings that miss critical information, even when used for something as simple as prescription labels.[12] However, they may have a role in translating specific medical terms that are misunderstood by patients who are otherwise fluent in English.

Table 1. Tips for Using a Medical Interpreter

Identify patients who may need an interpreter
Allow extra time for the interview
Meet with the interpreter before the interview to give some background, build rapport, and set goals
Document the name of the interpreter in the progress note
Realize that most patients understand some English, so do not make comments you do not want them to understand
Seat the interpreter next to or slightly behind the patient
Speak directly to the patient, not the interpreter
Use first-person statements ("I" statements); avoid saying "he said" or "tell her"
Speak in short sentences or short thought groups
Ask only one question at a time
Allow appropriate time for the interpreter to finish the statement
Prioritize and limit the key points to three or fewer
Do not use idioms, acronyms, jargon, or humor
Insist on sentence-by-sentence interpretation to avoid tangential conversations
Allow 10-minute breaks for every hour of interpretation
Use the "teach back" or "show me" technique to ensure patient comprehension
Have a post-session discussion with the interpreter to get further details and make corrections, if necessary

Using an Interpreter

Table 1 lists tips for using medical interpreters. It is best to meet briefly with the interpreter before the patient encounter to make sure he or she is the appropriate choice, give some clinical background, build rapport, and set goals.[13] This is especially important with untrained interpreters; coaching on technique can greatly facilitate the interview. The interviewer should speak in the first person ("I" statements), not the third person (e.g., "tell her," "he said"), and speak directly to the patient, whereas the

Table 2. Problems with Using Ad Hoc Nonprofessional Medical Interpreters

Children should not be used as interpreters except in emergencies because of their limited understanding of adult issues[8,16]
Family members may have personal agendas[17]
Interpreter may provide unsolicited advice[17]
No guarantee of confidentiality[17]
Nonprofessional interpreters are associated with a higher risk of longer hospital stays and readmission[18]
Physician may lose control of the interview because of tangential conversations[17]
Scope of inquiry may be limited when using a family member or friend because of embarrassment about intimate or sexual issues[8,13,17]
Unfamiliarity with medical terminology may lead to misunderstanding and errors in interpretation[4,8,17,19]

Information from references 4, 8, 13, and 16 through 19.

interpreter should function as an inconspicuous conduit for the conversation.[10] This is facilitated by seating the interpreter next to or slightly behind the patient.[10,13] The clinician should speak in short sentences, then wait for the interpreter to convey them.[6] Jargon, idioms, acronyms, and jokes should be avoided; attempts at humor are often lost in interpretation. Participants must aim for complete transparency, where everything said is interpreted for everyone present.[14] Because most patients comprehend at least some English, it is advisable to refrain from making comments that the patient should not hear.[10] Control of the interview is maintained by limiting tangential discussions.

Although interpreters function primarily as conduits for a discussion, they may secondarily serve as clarifiers, cultural liaisons, or patient advocates.[15] Clarification occurs when the interpreter interjects a brief explanation, often prefaced by the words "the interpreter would like to state… ." The interpreter can also function as a cultural liaison to help the clinician understand cultural beliefs about illness causation or care. The interpreter may even serve as a patient advocate by helping the physician understand barriers to dietary modifications, filling prescriptions, or proper follow-up.[15]

Common Pitfalls

The use of untrained interpreters is the proverbial "broad path of least resistance," resulting in many pitfalls. Ad hoc interpreters—usually friends or family—have multiple limitations *(Table 2)*.[4,8,13,16-19] The clinician does not know how effectively his or her message is being interpreted, which makes it easy to lose control of the interview. Nonprofessional interpreters have not received training about the Health Insurance Portability and Accountability Act and may not be aware of the need for confidentiality. Other potential problems include unfamiliarity with medical terminology, embarrassment about intimate or sexual issues (about which the interpreter may substitute euphemisms), unsolicited advice, and mixed motives or personal agendas.[17] The use of younger children as interpreters is especially problematic because of their limited understanding of adult issues,[16] and this practice is forbidden in several states. The use of nonprofessional interpreters increases the risk of nonequivalent interpretations, leading to possible misunderstandings.[19] Partially bilingual physicians face yet another pitfall: deciding to use their own limited language skills vs. hiring an interpreter. It is much easier to ask questions in another language than to understand the response. Overconfidence in one's language abilities can lead to serious errors and substandard care.[20]

Even when using a professional interpreter, care must be taken to avoid common mistakes *(Table 3)*. More than one-third of all Americans have limited health literacy, which leads to difficulties in navigating the complex U.S. health care system[21]; this is especially true for patients with limited English proficiency. Limiting the discussion

Table 3. Common Errors When Using Medical Interpreters

Error	*Correction*
Addressing the interpreter directly	Speak directly to the patient
Allowing the interpreter to dominate the conversation or answer for the patient	Insist on sentence-by-sentence interpretation and direct communication with the patient
Discussing multiple complex issues	Limit the key points to three or fewer
Permitting side conversations	Insist on sentence-by-sentence interpretation
Relying on one's own inadequate language skills	Use a qualified professional interpreter whenever possible
Seating the interpreter far away from the patient	Seat the interpreter next to or slightly behind the patient
Using an interpreter to witness a consent form	Use a noninvolved party to witness the consent
Using family or friends as interpreters	Use a qualified professional interpreter whenever possible
Using third-person statements (e.g., "tell her," "he said")	Use first-person statements ("I" statements)

to three major points may help avoid overwhelming the patient and interpreter.[22] Patients often do not understand directions, even though they may nod or say they do. It is best to use the "teach back" or "show me" technique, in which the patient is asked to repeat the directions in his or her own words.[22] If the patient is unable to do so, the directions should by explained again through the interpreter, and the patient should continue trying until he or she expresses full understanding.

Benefits and Requirements

The benefits of using professional interpreters are well documented *(Table 4)*.[4,5,8,15,17-19,23,24] In addition to clear interpretation with fewer errors, interviews with trained interpreters are associated with improved comprehension and significantly greater patient satisfaction,[23] better care and compliance, and lower risk of adverse events, thus mitigating malpractice risk.[17] The use of professional interpreters also reduces hospital stays and readmission rates.[18]

The National Standards for Culturally and Linguistically Appropriate Services include four mandates: (1) language assistance for patients with limited English proficiency should be offered at no cost; (2) patients should be notified of the availability of language assistance services in their preferred language, both verbally and in writing; (3) the competence of interpreters should be ensured, and the use of untrained persons or minors as interpreters should be avoided; and (4) easily understood print materials and signage should be provided in the languages commonly used in the service area.[24] Additionally, the Joint Commission, which accredits and certifies health care organizations in the United States, requires that hospital staff effectively communicate with patients when providing care, treatment, and services, and recommends language interpreters as one of the best options.[20] *Table 5* lists several online resources available to physicians.

Table 4. Benefits of Proper Use of Trained Medical Interpreters

Fewer errors in communication[4,8,19]
Improved patient satisfaction[4,17,23]
Interpreter may act as a cultural liaison to ensure clarification for the physician[15]
Interpreter may clarify patient meaning beyond language[15]
Interpreter may function as a link between patients and the health system[4,17]
Lower malpractice risk[15,17]
Use of a trained interpreter is associated with significantly shorter hospital stays and reduced 30-day readmission rates[18]
Use of a trained interpreter meets legal requirements of Title VI of the Civil Rights Act[5,15,24]

Information from references 4, 5, 8, 15, 17 through 19, 23, and 24.

Table 5. Medical Interpreter Resources for Physicians

A Physician's Practical Guide to Culturally Competent Care
https://www.thinkculturalhealth.hhs.gov/Content/ContinuingEd.asp (free continuing medical education course)
Agency for Healthcare Research and Quality – Overview of Medical Interpreter Standards of Practice
http://www.ahrq.gov/professionals/systems/hospital/lepguide/lepguidefig5.html
Certification Commission for Healthcare Interpreters
http://www.cchicertification.org (registry may be searched for certified interpreters)
Cross Cultural Health Care Program
http://www.xculture.org
DiversityRx
http://www.diversityrx.org
How to Communicate Effectively Through Interpreters: A Guide for Leaders
http://www.au.af.mil/au/awc/awcgate/army/using_interpreters.htm
National Board of Certification for Medical Interpreters
http://www.certifiedmedicalinterpreters.org (registry may be searched for certified interpreters)
National Council on Interpreting in Health Care
https://www.facebook.com/ncihc
National Standards for Culturally and Linguistically Appropriate Services in Health Care
http://http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53
Registry of Interpreters for the Deaf
http://www.rid.org (registry may be searched for certified interpreters)
Telephone interpreter services (fee-based)
CyraCom Language Solutions: http://www.cyracom.com
LanguageLine Solutions: http://www.languageline.com
MultiLingual Solutions: http://www.mlsolutions.com
Telelanguage: http://www.telelanguage.com

Data Sources: We searched PubMed, Clinical Evidence, the Cochrane Database of Systematic Reviews, and Medline (Ovid) using the terms medical interpretation, interpretation for the deaf, interpretation techniques, ethics for interpreters, limited English proficiency, language barriers in medicine, telephone interpretation, certification of health care interpreters, health literacy, teach back, and National Standards for Culturally and Linguistically Appropriate Services (CLAS). Search dates: May 2013 to August 2014.

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Policy and Procedure

Policy Name:	Advance Health Care Directive Policy		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL California Probate Code, Section 4701, 42 CFR 422.128, 42 CFR 489.100, and APL 05-010 AB 3000, Chapter 266, Statutes of 2008, available at: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=200720080AB3000		

Purpose:

To identify adult patients (18 years and older or emancipated minors) have been offered information on Advance Health Care Directives (AHCD) and, if executed, patient's preferences are maintained within the Medical Record.

Definitions:

Advance medical directives: These directives pertain to treatment preferences and the designation of a surrogate decision-maker if a person should become unable to make medical decisions on their own behalf. Advance directives generally fall into three categories: living will, power of attorney and health care proxy.

A living Will

- This form lets you list the care you want at the end of your life
- A living will applies only if you won't live without medical treatment. It would apply if you had advanced cancer or a massive stroke
- It takes effect only when you can no longer express your wishes yourself

A Durable Power of Attorney for Health Care

- This form lets you name someone else to be your agent.
- This person can decide on treatment for you only when you can't speak for yourself.
- You do not need to be at the end of your life. He or she could speak for you if you were in a coma but more likely to recover.

A health care proxy is a document that names someone you trust as your proxy, or agent, to express your wishes and make health care decisions for you if you are unable to speak for yourself. A health care proxy may also be called a durable medical power of attorney or an appointment of a health care agent or health care surrogate.

Policy:

- Adult (18 years and older or emancipated minors) medical records include documentation of whether the member has been offered information or has executed an AHCD
- Advance Health Care Directive Information is reviewed with the member at least every 5 years and as appropriate to the member's circumstance.
- Physician Orders for Life-Sustaining Treatment (POLST) form and Five Wishes are acceptable if appropriately completed and signed by the necessary parities.

Procedure:

1. Provide AHCD information
2. Discuss AHCD preferences with patient
3. Document information provided, completed AHCD in patient's Medical Record or document patient's declination to execute.
    a. Optional - Provide other options: POLST/Five Wishes and document in patient's Medical Record

Resource:

1. AHCD Workflow sample attached

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

Advance Health Care Directive (AHCD) Work Flow

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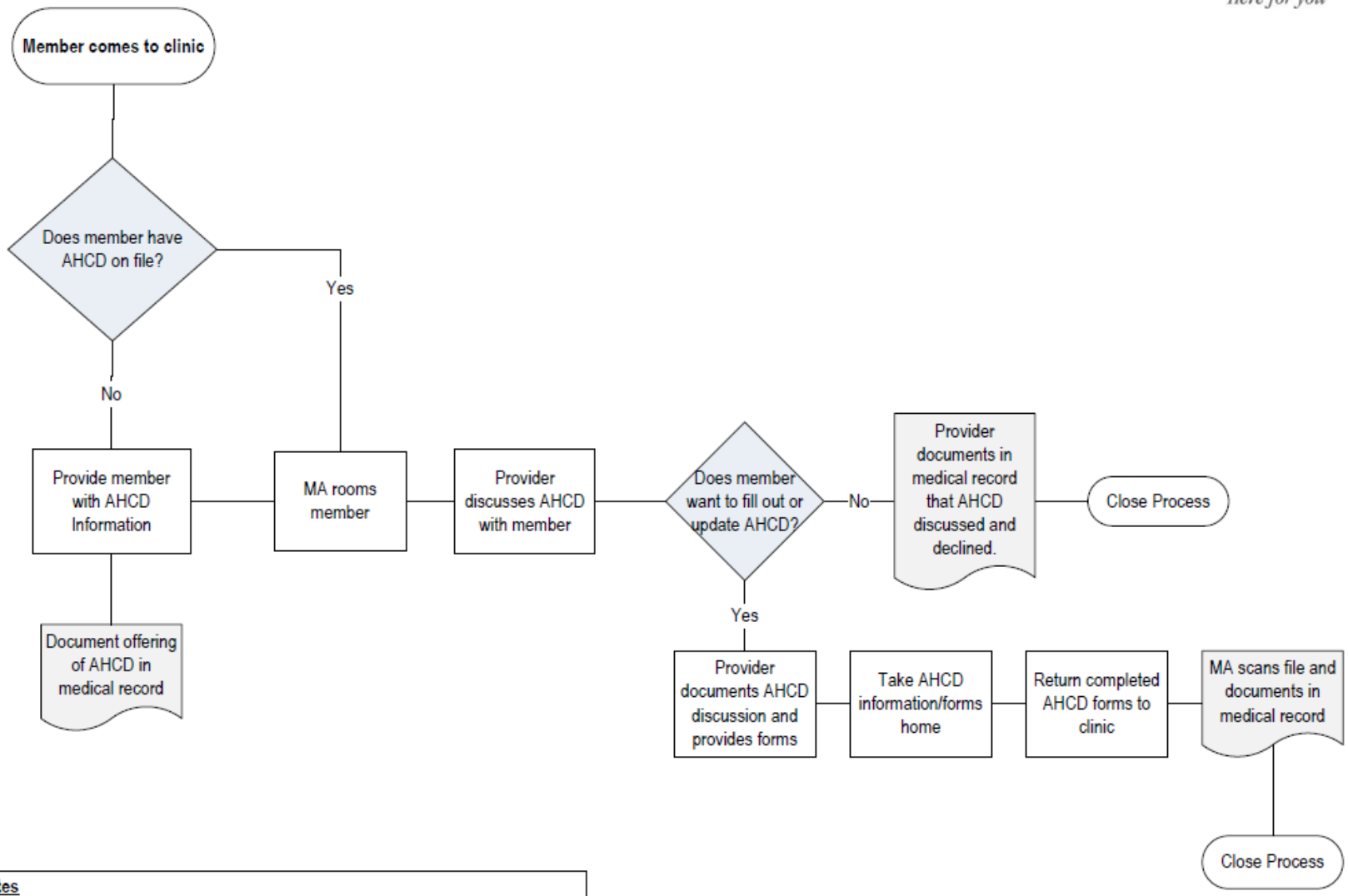


Notes
1. All members 18 years or older are offered AHCD information.
2. AHCD reviewed with member at least every 5 years and as appropriate to member's circumstance
3. Physician Orders for Life-Sustaining Treatment (POLST) form or Five Wishes are acceptable if appropriately completed and signed by necessary parties

SFHP FSR, 2022

加州預立醫療指示資訊

填寫本表單以便在病重時表達治療的意願。本表單可讓您：

- **選擇一名健康護理代理人。**當您病得太重而無法自己做醫療決定時，健康護理代理人能幫您做決定。
- **做出您自己的健康護理選擇：**您可以選擇您想要哪類的健康護理；如此一來，當您病得太重而無法自己做決定時，您的照顧者就不必猜測您的想法。

如果我不選擇一名健康護理代理人，會如何？

當您病得太重而無法自己做決定時，您的醫生將請您最親近的家屬幫您做決定。如果您想選擇家屬以外的人當代理人，您必須將他/她的姓名寫在這份表單上。

我的健康護理代理人可以做什麼樣的決定？

同意、否決、更改、停止或選擇：

- ✓ 醫生、護士、社工
- ✓ 醫院或診所
- ✓ 藥物或檢驗
- ✓ 您去世後，遺體和器官的處理方式

您的代理人還可能做其他決定：

- ✓ **維生治療** – 設法幫助您延長生命的醫療護理
- ✓ **CPR 心肺復甦術** - 可能包括：
  - 用力壓您的胸，保持您的血液打進身體各部位
  - 施以電擊，讓您的心臟恢復跳動
  - 將藥物注入您的靜脈
- ✓ **呼吸器** - 這類機器能將空氣打進您的肺部並幫助您呼吸。當您使用呼吸器時，將無法說話。
- ✓ **洗腎透析** - 當您的腎臟停止作用時，用機器幫您清血液。
- ✓ **餵食管** - 當您無法吞嚥時，用管子為您餵食。管子可從喉嚨插進您的胃，亦可用手術放入您的胃。
- ✓ **輸血** - 將血液注入您的靜脈。
- ✓ **手術**
- ✓ **藥物**
- ✓ **臨終護理** – 如果您可能不久人世，您的健康護理代理人可以：

- 請一位心靈帶領者過來
- 決定讓您在家裡或醫院過世

您的健康護理提供者將回答您對這份重要文件的任何問題。

~ 如果您想要一份預立醫療指示表單，請向診所工作人員索取 ~

關於預立醫療指示的更多資訊，請瀏覽：

https://www.sfhp.org/providers/provider-forms/

California Advance Health Care Directive Information

This form lets you have a say about how you want to be treated if you get very sick. It lets you:

- **Choose a health care agent.** A health care agent is a person who can make medical decisions for you if you are too sick to make them yourself.
- **Make your own health care choices.** You can choose the kind of health care you want so if you are too sick to decide for yourself, those who care for you will not have to guess what you want.

What will happen if I do not choose a health care agent?
If you are too sick to make your own decisions, your doctors will ask your closest family members to make decisions for you. If you want your agent to be someone other than family, you must write his or her name on the form.

What kind of decisions can my health care agent make?
Agree to, say no to, change, stop or choose:

- ✓ doctors, nurses, social workers
- ✓ hospitals or clinics
- ✓ medications or tests
- ✓ what happens to your body and organs after you die

Other decisions your agent can make:

- ✓ **Life support treatments –** medical care to try to help you live longer
- ✓ **CPR or cardiopulmonary resuscitation** - This may involve:
  - pressing hard on your chest to keep your blood pumping
  - electrical shocks to jump start your heart
  - medicines in your veins
- ✓ **Breathing machine or ventilator** - The machine pumps air into your lungs and breathes for you. You are not able to talk when you are on the machine.
- ✓ **Dialysis** - A machine that cleans your blood if your kidneys stop working.
- ✓ **Feeding Tube** - A tube used to feed you if you cannot swallow. The tube is placed down your throat into your stomach. It can also be placed into your stomach by surgery.
- ✓ **Blood transfusions** - To put blood in your veins.
- ✓ **Surgery**
- ✓ **Medicines**
- ✓ **End of life care –** if you might die soon your health care agent can:

– call in a spiritual leader
– decide if you die at home or in the hospital

Your health care provider will answer any questions you may have about this important document.

~ If you want an Advance Directive form ask a member of the clinic staff.

For more information about the Advance Health Care Directive visit https://www.sfhp.org/providers/provider-forms/

Информация о предварительном медицинском указании для штата Калифорния

Посредством этого бланка Вы сможете выразить свои пожелания относительно лечения на случай, если Вы тяжело заболеете. Этот документ позволяет Вам:

- **Выбрать представителя по вопросам лечения.** Представитель по вопросам лечения — это человек, которому разрешается принимать медицинские решения вместо Вас в ситуациях, когда Вы находитесь в тяжелом состоянии и не можете принимать решения самостоятельно.
- **Сделать собственный выбор в отношении медицинского обслуживания.** Вы можете указать, какое именно медицинское обслуживание Вам следует предоставлять в случае, когда состояние Вашего здоровья не позволяет Вам принимать решения. Лица, оказывающие Вам медицинскую помощь, будут действовать в соответствии с Вашими указаниями.

Что если я не выберу представителя по вопросам лечения?
Если Вы окажетесь в ситуации, когда состояние Вашего здоровья не позволит Вам принимать решения самостоятельно, врачи обратятся к ближайшим родственникам, чтобы они принимали решения вместо Вас. Если Вы хотите, чтобы такие решения принимал человек, не являющийся Вашим родственником, Вы должны указать его или ее имя в этом документе.

Какого рода решения сможет принимать мой представитель по вопросам лечения?
Он может принять рекомендации, отклонить их, заменить, отменить или выбрать:

- ✓ врачей, сестринский(-ого) персонал(-а), социальных работников
- ✓ больницы или клиники
- ✓ лекарства или анализы
- ✓ действия с Вашим телом или органами после смерти

Ваш представитель также может принимать решения по следующим вопросам:

- ✓ **Лечение, направленное на поддержание жизнедеятельности** — медицинское обслуживание в целях попытаться продлить Вашу жизнь
- ✓ **Сердечно-легочная реанимация** — может включать следующие действия:
  - сильные нажатия на грудную клетку, чтобы поддерживать перекачивание крови по телу
  - воздействие электрическим разрядом, чтобы запустить работу сердца
  - внутривенное введение лекарств
- ✓ **Аппарат искусственного дыхания** — он нагнетает воздух в легкие и дышит вместо вас. Когда пациент подключен к такому аппарату, он не может говорить.
- ✓ **Диализ** — процедура очистки крови на специальном аппарате в ситуациях, когда не работают почки.
- ✓ **Зонд для питания** — трубка, которая используется для кормления, если человек не может глотать. Эту трубка проходит через горло в желудок. Также ее можно ввести в желудок при помощи хирургического вмешательства.
- ✓ **Переливания крови** — процедура, при которой в вену вводят кровь.
- ✓ **Хирургическое лечение**
- ✓ **Лекарства**
- ✓ **Уход до конца жизни** — если есть вероятность близкой смерти, представитель по вопросам лечения может:

– позвонить духовному лицу
– решить, следует ли Вам оставаться в больнице или вернуться домой

Ваш поставщик медицинских услуг ответит на все вопросы, касающиеся этого документа.

~ Если Вам нужен бланк предварительного указания, скажите об этом персоналу клиники ~

Более подробные сведения о предварительном медицинском указании представлены на веб-странице https://www.sfhp.org/providers/provider-forms/

Información de Cuidado Médico por Adelanto de California

Esta forma deja que usted indique como usted quiere ser atendido en el caso que muy enfermo. Le deja:

- **Escojer a un representante para la atención a la salud.** Un representante para la atención a la salud es una persona que puede tomar decisiones médicas en su nombre si usted está demasiado enfermo para hacerlo.
- **Hacer sus propias decisiones sobre su cuidado médico.** Le permite escojer qué tipo de atención médica qué usted desea. De esta manera, los quien lo atiendan no tendraán qué adivinar qué desea usted si está demasiado enfermo para decirles ustes mismo.

¿Qué pasa si no elijo a un representante de atención a la salud?
Si usted está demasiado enfermo para tomar sus propias decisiones, sus médicos le pedirán a sus familiares más cercanos que tomen decisiones en su nombre. Si usted desea que su representante sea alguien fuera de su familia, debe escribir el nombre de la persona en esta forma.

¿Qué tipo de decisiones puede tomar mi representante?

Dar permiso, rechazar, cambiar, parar, o elegir:

- ✓ a sus médicos, enfermeras, y trabajadores sociales
- ✓ sus hospitales o clínicas
- ✓ medicinas o exámenes medicos
- ✓ decidir que va a pasar con su cuerpo y órganos después que usted muera

Otras decisiones que puede tomar mi representante

- ✓ **Tratamientos para mantener la vida** -atención médica para tratar de ayudarle a vivir mas tiempo
- ✓ **RCP o resucitación cardio-pulmonar** - Esto puede incluir:

– presionar fuertemente sobre su pecho para mover su sangre
– toques elétricos para “pasar corriente” a su corazón
– darle medicinas por las venas

- ✓ **Máquina para respirar o ventilador mecánico** - La máquina bombea aire a sus pulmones y respira por usted. Usted no puede hablar cuando esta conectado a la máquina
- ✓ **Diálisis** - Un aparato que limpia su sangre si sus riñones dejan de funcionar
- ✓ **Sonda de alimentación** Un tubo que se usa para alimentarlo si usted no puede tragar. Se pone por la garganta hasta el estómago. También se pone con una operación
- ✓ **Transfusioines de sangre** - Dar sangre por sus venas
- ✓ **Cirugía**
- ✓ **Medicamentos**
- ✓ **Cuidados al fin de la vida –** si usted se esta muriendo su representante podrá:

– llamar a un lider espiritual.
– decidir si usted se muere en casa o en el hospital.

El médico responderá cualquier pregunta que pueda tener sobre este documento importante.

Si desea una forma de Cuidado Médico por Adelanto, pidasela a un miembro del personal de la clínica.

Para más información acerca de la directiva anticipada de atención de salud, visite https://www.sfhp.org/providers/provider-forms/

Impormasyon sa Nauna nang Naitakdang Kautusan sa Pangangalaga sa Kalusugan ng California (California Advance Health Care Directive Information)

Binibigyan kayo ng pagkakataon sa form na ito na magsabi kung paano ninyo gustong magamot kapag nagkaroon ng malubhang karamdaman. Pinahihintulutan nito kayong:

- **Pumili ng kinatawan sa pangangalaga sa kalusugan (health care agent).** Ang kinatawan sa pangangalaga sa kalusugan ang taong makakapagdesisyon para sa inyo kaugnay ng paggamot sa inyo kung labis na kayong nasa malubhang kalagayan para magpasya para sa sarili.
- **Gawin ang sariling desisyon para sa pangangalagang pangkalusugan.** Mapipili ninyo ang uri ng pangangalagang pangkalusugan gusto ninyo kung masyado nang malubha ang kalagayan ninyo para makapagpasya pa para sa sarili, at hindi na kailangan manghula ng mga nagangangalaga sa inyo kung ano ang gusto ninyo.

Ano ang mangyayari kapag hindi ako pumili ng kinatawan sa pangangalaga sa kalusugan?
Kung masyado nang malubha ang kalagayan ninyo para makapagpasya pa para sa sarili, hihilingin ng inyong mga doktor sa inyong pinakamalapit na kapamilya na magpasya para sa inyo. Kung gusto ninyo ng kinatawan bukod sa inyong pamilya, kailangang isulat ninyo ang pangalan niya sa form.

Anong uri ng mga desisyon ang magagawa ng aking kinatawan sa pangangalaga sa kalusugan?
Sumang-ayon, humindi, baguhin, magpatigil o mamili ng:

- ✓ mga doktor, nars, social worker
- ✓ mga ospital o klinika
- ✓ mga paggamot o test
- ✓ kung ano ang mangyayari sa inyong katawan o mga organo pagkamatay ninyo

Iba pang mga desisyon na magagawa ng inyong kinatawan:

- ✓ **Mga paggamot na pansuporta sa buhay –** medikal na pangangalaga na sumusubok na pahabain pa ang inyong buhay
- ✓ **Pagpapanumbalik ng hininga (CPR o cardiopulmonary resuscitation)** - puwedeng kasama rito ang:
  - mariing pagdiin sa inyong dibdib para mapanatiling dumadaloy ang inyong dugo
  - de-koryenteng paggulat (electrical shock) para pumintig muli ang inyong puso
  - mga gamot sa inyong ugat
- ✓ **Makinang para sa paghinga (breathing machine or ventilator)** - Nagdadala ng hangin sa baga ninyo ang makinang ito at humihinga para sa inyo. Hindi kayo makapagsasalita habang gumagamit kayo ng makinang ito.
- ✓ **Dialysis** - Ang makinang maglilinis sa dugo ninyo kapag pumalya na ang inyong bato.
- ✓ **Tubo sa Pagkain (Feeding Tube)** - Ang tubo na magpapakain sa inyo kapag hindi na kayo makalunok. Ipinapasok ang tubo sa lalamunan ninyo papunta sa bituka. Maipapasok din ito sa inyong bituka sa pamamagitan ng pag-oopera.
- ✓ **Pagsasalin ng dugo** - Upang masalinan ng dugo ang inyong mga ugat.
- ✓ **Pag-oopera**
- ✓ **Mga gamot**
- ✓ **Pangangalaga sa mga Huling Sandali ng Buhay (End of life care) –** kung hindi magtatagal at mamamatay na kayo, magagawa ng inyong kinatawan na:

– tumawag ng espiritwal na lider
– magpasya kung sa bahay o ospital kayo mamamatay

Sasagutin ng inyong tagabigay ng pangangalagang pangkalusugan ang anumang katanungan tungkol sa mahalagang dokumentong ito.

~ Kung gusto ninyo ng form ng Nauna nang Naitakdang Kautusan (Advance Directive), hingin ito sa sinuman sa mga kawani ng klinika ~

Para sa karagdagang impormasyon tungkol sa Nauna nang Naitakdang Kautusan na Pangangalaga sa Kalusugan bisitahin ang https://www.sfhp.org/providers/provider-forms/

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Subject:	Release of Medical Records
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	Title 45, Code of Federal Regulations Section 164.524. The CFR is searchable at: https://www.ecfr.gov Confidentiality of Medical Information Act CALIFORNIA CIVIL CODE SECTIONS 56-56.16 Health Insurance Portability and Accountability Act (HIPAA) sets national standards for the security of electronically stored or transmitted medical data. 22 CCR 73524, 22 CCR 51009, and Title 45, Code of Federal Regulations Section 164.524
Agency/Organization Source:	
Agency/Organization URL	

Background:

Medical records are considered highly sensitive, available only to those who need to know and/or have been given consent. Federal laws, CFR § 164.520, govern the privacy protection of medical records, along with some state laws. California Health & Safety Code Section 123100 et seq. establishes a patient's right to see and receive copies of his or her medical records, under specific conditions and/or requirements. California medical records laws state that a patient's information may not be disclosed without authorization unless it is pursuant to a court order, or for purposes of communicating important medical data to other health care providers, insurers, and other interested parties.

Purpose:

A system must be in place at the clinic to assure the confidentiality of client records. The system is compliant with State and Federal Regulations when a release of protected health information is requested.

Definitions:

1. Medical Information is any individually identifiable information that is kept in either physical or electronic form.

2. Medical Record is any recorded information, regardless of medium or characteristics. A "medical record" includes both clinical and non-clinical information, from the patient's medical history and demographics to relevant clinical research and financial data. There is no one-size-fits-all definition, and your practice should clearly define a "medical record" as it relates to the systems in place at your individual practice.

Procedure:

1. Parties required to comply with the Medical Information Act include heath care providers, health care service plan providers (insurers), pharmaceutical companies, and any other entities involved in handling sensitive medical data.
2. Ensure the security of electronically stored or transmitted medical data according to the federal Health Insurance Portability and Accountability Act (HIPAA)
3. A primary care provider must permit the patient to view his or her records during business hours within five working days after receipt of the written request.
4. A valid authorization to release protected health information includes:
    a) Identity verification such as a driver's license.
    b) A description of the information to be used or disclosed.
    c) The name of the person or organization authorized to disclose the information.
    d) The name of the person or organization that the information is to be disclosed.
    e) Signature of the person authorized to release the information.

Resource:

1. Find sample ROI authorization form attached

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

Appendix A:

AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

I, _____, hereby authorize _____ to
(Name of individual) (Name of person or facility which has information)

release the following health information:

_____

To:

_____
(Name of person/title or facility to receive health information)

_____ _____ _____
(Street address, city, state, ZIP code) (Telephone number) (Fax number)

For the purpose of: _____

_____

This authorization is in effect until _____ (date or event) when it expires.

I understand that by signing this authorization:

- I authorize the use or disclosure of my individually identifiable health information as described above for the purpose listed.
- I understand that this authorization is voluntary.
- I understand the Notice of Privacy Practices provides instructions should I choose to revoke my authorization.
- I understand if the organization I have authorized to receive the information is not a health plan or health care provider, the released information may no longer be protected by federal privacy regulations.
- I understand I have the right to receive a copy of this authorization.
- I understand that I am signing this authorization voluntarily and that treatment, payment, or eligibility for my benefits will not be affected if I do not sign this authorization.

I DECLARE UNDER PENALTY OF PERJURY THAT THE INFORMATION ON THIS FORM IS TRUE AND CORRECT

Signature **Date**

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Legal Documentation of Error Correction		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:
Errors are corrected according to legal medical documentation standards. This procedure allows for both the original entry and corrected entry to be clearly preserved

Policy:
The person that makes the documentation error corrects the error. One correction method is (single line drawn through the error, with the writer's initial and date written above or near the lined-through entry). Similar variations such as (single line and initial) are also used. The corrected information is written as a separate entry and includes date of the entry, signature (or initials), and title. There are no unexplained cross-outs, erased entries or use of correction fluid.

Procedure:

S.L.I.D.E. = Single, Line, Initial, Dated, Error

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

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.

SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Referral Process Flow Information
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	
Agency//Organization Source:	
Agency/Organization URL	

Background:

An organized, timely referral system is clear for making and tracking referrals, reviewing reports, providing/scheduling follow-up care and filing reports in medical records. Referral informational resources are readily available for use by site personnel. Site staff can demonstrate (e.g., "walk through") the office referral process from beginning to end.

Purpose:

Procedures for timely referral/ consultative services are established on site.

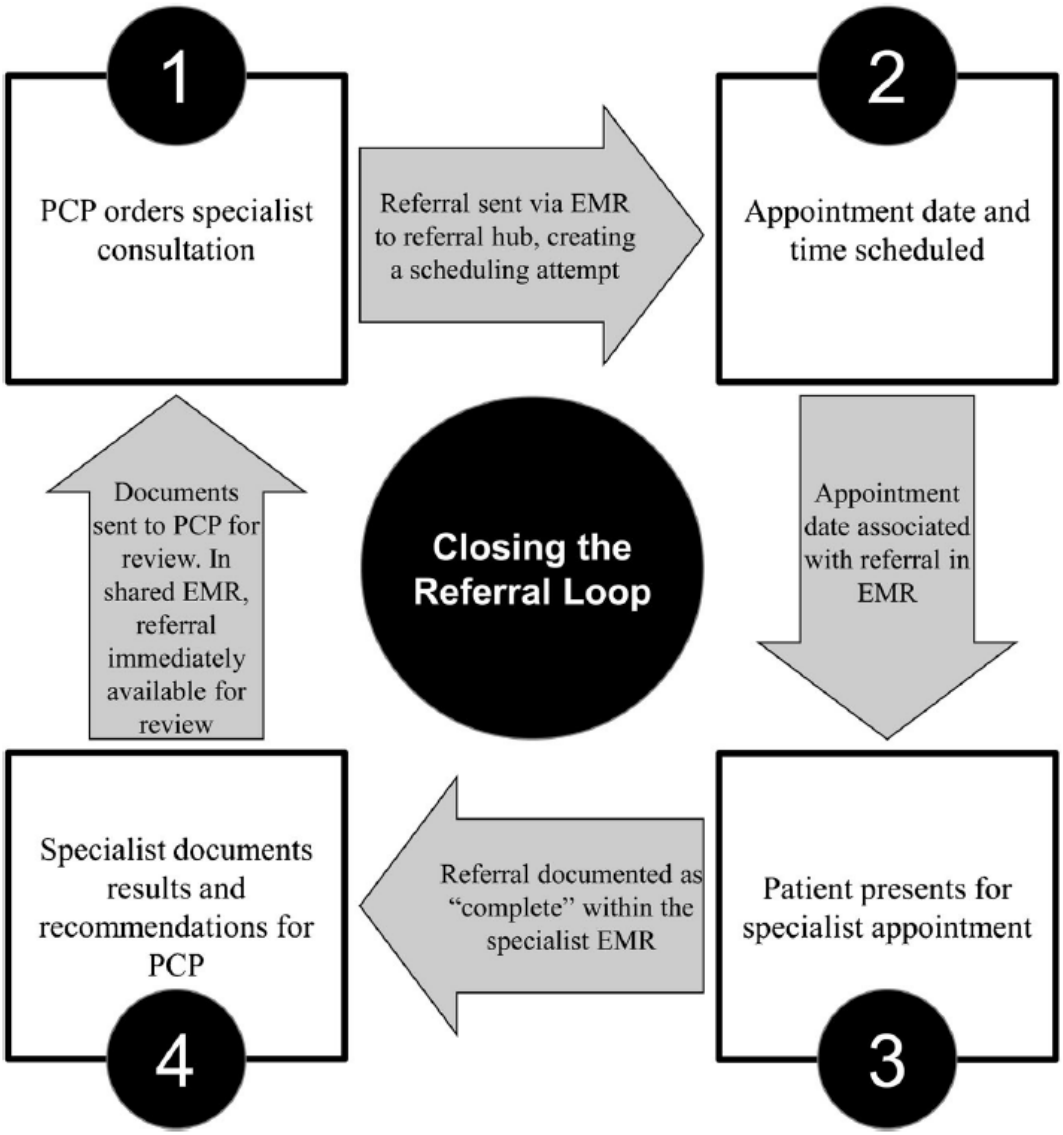
Requirements:

- Evidence of review may include the practitioner's initials or signature on the report, notation in the progress notes, or other site-specific method of documenting practitioner review.
- Electronically maintained medical reports must show evidence of practitioner review.
- Evidence of practitioner review on any page of the report(s) or diagnostic result(s) that have multiple pages is acceptable.
- Evidence of explicit notation in the medical record or separate system of referral tracking, including attempts to contact the member/guardian, as indicated.

Resource:

- Agency for Healthcare Research and Quality (AHRQ), Make Referrals Easy
    - https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2_tool21.pdf

Closing the Referral Loop



Source: Patel, M. P., Schettini, P., O'Leary, C. P., Bosworth, H. B., Anderson, J. B., & Shah, K. P. (2018). Closing the referral loop: an analysis of primary care referrals to specialists in a large health system. Journal of general internal medicine, 33(5), 715-721.

Make Referrals Easy — Tool 21

Overview

Primary care practices refer patients to specialists, ancillary health care clinicians, labs and screening facilities, and elsewhere. Making the referral process easy for patients increases the chances that they will follow through, and that both you and the referral destination get all the information you need.

Actions

Refer patients to clinicians who coordinate care with you.

- Identifying, developing, and maintaining relationships with clinicians to whom you refer patients can make the referral process run smoothly.
- **Try to establish formal referral agreements** with key specialist groups and other clinicians.
- Don't continue to refer patients to clinicians who do not send information back to you, don't provide timely appointments for your patients, or otherwise fail to coordinate care.

Referral Agreements

Referral agreements spell out mutual expectations and responsibilities, such as:

- Which patients are appropriate to refer
- What information is needed before and after a referral
- Roles for both parties after the referral
- Setting aside appointments for urgent care

Don't rely on patients to relay information.

- **Share important information directly with the other office**, such as the reason for the referral, pertinent medical history, and test results.
- **Explore making electronic referrals.** Check whether your EHR has the capability to make referrals directly to other clinicians. If not, self-standing referral management systems are commercially available for purchase.
- Provide a detailed referral to the other clinician that contains all the information needed. The Improving Chronic Illness Site has a guide on Reducing Care Fragmentation, which includes a checklist of information to provide to specialists for each referral.
- **Get information sent directly back to you.** Make sure you get a full report back before your patient's next visit.

Consider language barriers.

- When making referrals for patients with limited English proficiency, **identify clinicians who are language concordant or have interpreter services**. See Tool 9: Address Language Differences for more information on language assistance.
- **Include information on your patient's language assistance needs** when making the referral.

Make sure the patient understands the reason for the referral.

- **Explain why** the patient needs to be seen by someone else, and what might happen if he or she is not seen.
- In the case of tests, **explain how you and the patient will use the information** to diagnose, manage, or decide on treatments for health conditions.
- In the case of screenings, **give a clear explanation of the risks and benefits.** Ultimately, it's up to the patient as to whether or not to undergo any particular test or screening.
- **Use the teach-back method** (see Tool 5: Use the Teach-Back Method) to confirm patient understanding.
- **Ask about and address any concerns or fears**.

Offer help with the referral.

- Ask patients if they would like your office to make the initial phone call.
- If staff members are making appointments for patients, make sure they first find out when the patients are available.
- Ask patients about transportation and other barriers to their completing the referral. Discuss how they could overcome these barriers. Use Tool 18: Link Patients to Non-medical Support to refer them to other services that could support their completion of the referral.

Provide clear instructions.

- For some referrals, patients will need to prepare in advance (e.g., fast, discontinue a medicine). Provide easy-to-understand instructions verbally and in writing.
- Explain the referral process fully (e.g., how you and the other clinician will exchange information, when the patient should return to your office).
- Give clear oral and written directions to get to the referral location.
- Use the teach-back method (see Tool 5) to confirm patient understanding.

Follow up on referrals.

- Confirm and document that the patient successfully completed the referral.
- Obtain information on the result of the referral and document in the medical record.
- Make sure the patient receives the results of any tests or screenings, even normal results.
- Provide patients positive feedback for completing referrals. Let patients see how you use the information obtained from tests or specialist visits.

- If the patient has not completed the referral, reinforce that you feel the patient could benefit, and review barriers.
- Determine whether the patient needs additional referrals.
- Get feedback from patients on the quality of the care provided. Stop making referrals to places that consistently receive negative reports.

Track Your Progress

Select a sample of referrals made during a week. Examine the referral records to calculate the percentage of referrals that included all relevant information. One month later, calculate the percentage of patients whose referral results are in their medical records.

Select a sample of patients who were sent for lab tests during a week. One month later, calculate the percentage of patients who have completed the test and the percentage who have been notified of the test results.

One month after implementing this Tool, ask a sample of patients who have not completed referrals why they did not follow through. Develop and implement an improvement plan to address the reasons they give. Repeat in 2, 6, and 12 months.

Resources

Care Coordination: Relationships and Agreements describes a package of changes, activities, and resources for primary care practices seeking to improve coordination.

Improving Your Office Testing Process: A Toolkit for Rapid-Cycle Patient Safety and Quality Improvement contains tools for referring to patients and following up on tests.

Sample Referral Log

Referral Date	Patient's Name	D.O.B.	Provider Referred To	Specialty	Date of Appt	Date Consult Recv'd	7 Day Follow-up	30 Day Follow-up

Referral Log

Date Referral sent to IPA	Patient Name and/or Medical Record Number	Referred to: Specialist/ Facility	Auth. Status & Date Approved/ Denied/ Deferred	Date Patient notified	Date of Appt / Services	DATE REPORT RECEIVED AND/OR COMMENTS

*Acuity of Referral: Emergent, Urgent or Routine

Referral Log

Date Referral sent to IPA	Patient Name and/or Medical Record Number	Referred to: Specialist/ Facility	Auth. Status & Date Approved/ Denied/ Deferred	Date Patient notified	Date of Appt / Services	DATE REPORT RECEIVED AND/OR COMMENTS

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*Acuity of Referral: Emergent, Urgent or Routine

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Initial Health Assessment (IHA) and IHEBA (Individual Health Education Behavior Assessment): Pediatric and Adult		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL IHA PL 08 – 003 or current version IHEBA PL 13-001 or current version		

Purpose:

The Initial Health Assessment (IHA) includes a comprehensive history and Individual Health Education Behavior Assessment (IHEBA). The IHA enables the PCP to assess current acute, chronic, and preventive needs and to identify those members whose health needs require coordinated services with appropriate community resources/other agencies not covered by the health plan. IHA must be completed within 120 days of plan enrollment or documented within the 12 months prior to health plan enrollment.

(References: IHA PL 08 – 003 or current version; IHEBA PL 13-001 or current version)

Definition:

Initial Health Assessment (IHA): Comprehensive history plus an Individual Health Education Behavioral Assessment

Individual Health Education Behavior Assessment (IHEBA): An age-appropriate behavioral assessment tool. These assessment tools may assist in screening for risk factors for many preventive care criteria (e.g., alcohol misuse, STI, HIV, Tobacco, etc.)

Policy:

1. A new member must be given an IHA within 120 days of plan enrollment or evidence of a previous IHA must be documented within the 12 months prior to plan enrollment
2. An IHA includes the following:
    a. Comprehensive History and Physical (H & P)
        i. History of present illness
        ii. Past medical history

iii. Social history
iv. Review of Organ Systems (ROS)

3. An age appropriate IHEBA tool must be given to a new member and periodically reviewed and updated
    a. DHCS Staying Healthy Assessment (Pediatric, Adult, and Senior)
    b. AAP Bright Futures (Pediatric)
    c. Other DHCS approved IHEBA tool
4. Site will follow re-administration periodicity according to established IHEBA periodicities on the tool being used
    a. Adolescents and Seniors should have IHEBA re-administered annually due to frequently changing risk factors, or more frequently based on member's health and medical status
    b. Adults should have IHEBA re-administered every 3-5 years, or more frequently based on member's health and medical status
5. There must be evidence of practitioner review of the IHEBA on the assessment form or progress note within the medical record
    a. Printed name
    b. Signature
    c. Date
    d. Interventions, which may be documented on the IHEBA form, in progress notes, or other areas of the paper or electronic medical record system
6. Member refusal to complete an IHEBA or SHA
    a. Declination of the IHEBA should be documented in the medical record
    b. Member should be encouraged to complete the IHEBA each subsequent year during scheduled exams
        i. Continue to document continued refusal to complete the IHEBA in the medical record

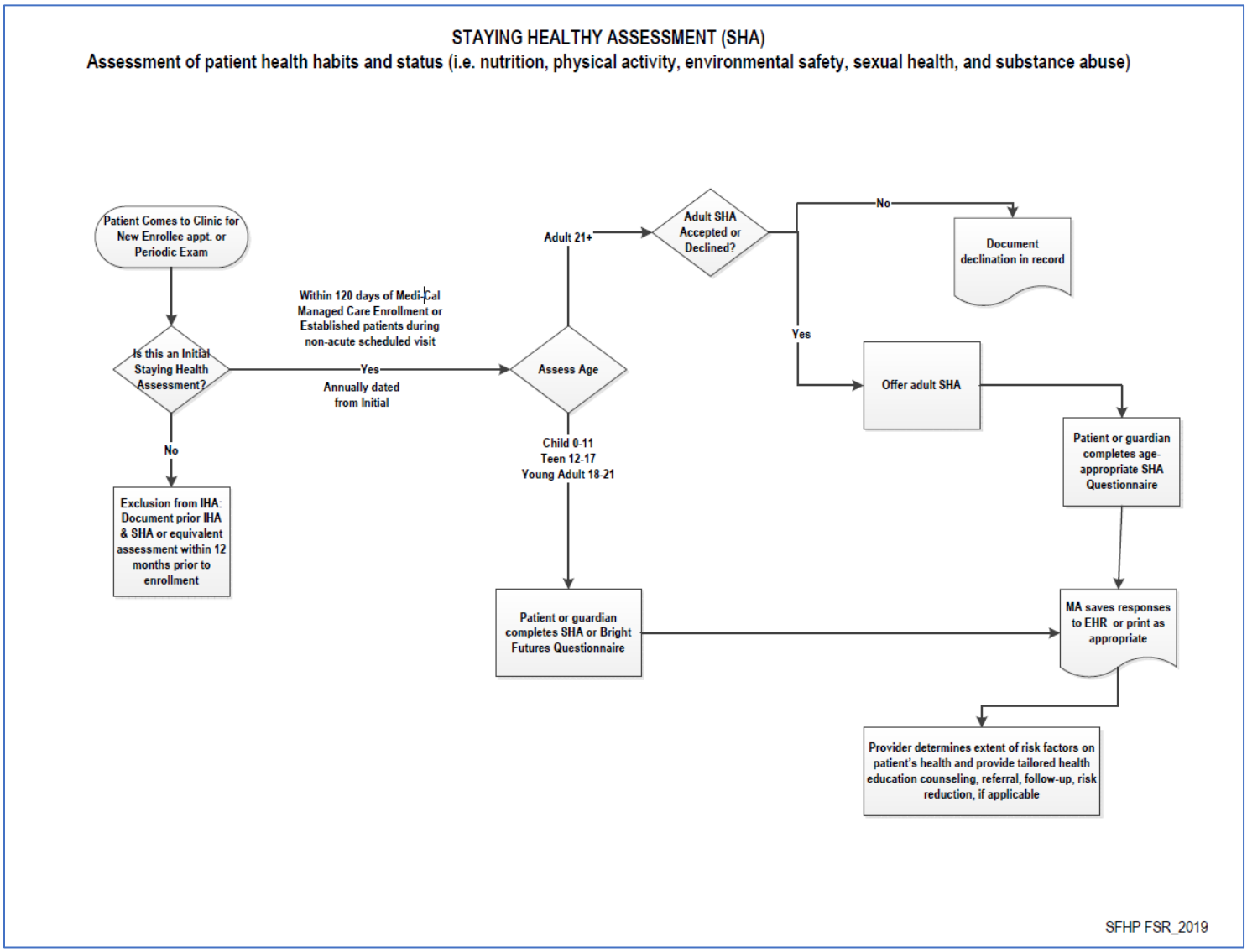
Resources:

- Resource 1: DHCS Staying Health Assessment Questionnaires
- Resource 2: AAP Bright Futures

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

Procedure/Workflow Example: (Paper-based)



SAN FRANCISCO HEALTH PLAN
Here for you

Resource Guide

Subject:	Autism Spectrum Disorder (ASD) Screening
Facility Site Review Source:	
Relevant Law/Standard:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL DHCS APL 18-006 and APL 18-007 or current versions. Refer to APL 19-014, Responsibilities for Behavioral Health Treatment Coverage for Members Under the Age of 21 APL 19-010, Requirements for Coverage of Early and Periodic Screening, Diagnostic, and Treatment Services for Medi-Cal Members Under the Age of 21, or any superseding APLs
Agency//Organization Source:	Nation Institute of Mental Health
Agency/Organization URL	https://www.nimh.nih.gov/index.shtml

Background:

Autism spectrum disorder (ASD) is a developmental disorder that affects communication and behavior. Although autism can be diagnosed at any age, it is said to be a developmental disorder" because symptoms generally appear in the first two years of life.

Autism Spectrum Disorder Screening must be performed at 18 months and 24 months based on AAP periodicity "Bright Futures". If the patient is positive for risk factors, provider shall offer and document appropriate follow-up intervention(s).

Autism Spectrum Disorder Screening tools that may be used are:

- Ages and Stages Questionnaires (ASQ)
- Communication and Symbolic Behavior Scales (CSBS)
- Parents' Evaluation of Developmental Status (PEDS)
- Modified Checklist for Autism in Toddlers (MCHAT)
- Screening Tool for Autism in Toddlers and Young Children (STAT)
- Survey of Well-being of Young Children (SWYC) screening tools (assess three domains of child functioning: developmental domain, emotional/behavioral domain, and family context)

Purpose:

Doctors diagnose ASD by looking at a person's behavior and development. ASD can usually be reliably diagnosed by the age of two. It is important for those with concerns to seek out assessment as soon as possible so that a diagnosis can be made, and treatment can begin.

Resources:

- **ASQ** https://agesandstages.com/screening-navigator/screening/

- **CSBS** https://firstwords.fsu.edu/pdf/Checklist_Scoring_Cutoffs.pdf
- **PEDS** https://pedstest.com/
- **MCHAT** https://mchatscreen.com/wp-content/uploads/2015/09/M-CHAT-R_F_Rev_Aug2018.pdf
- **STAT** https://vkc.mc.vanderbilt.edu/vkc/triad/stat/

SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	Psychosocial/Behavioral Assessment
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	IDEA Part H (Public Law 99-457(1986)/ Early Start Program
Agency//Organization Source:	American Academy of Pediatrics (AAP)
Agency/Organization URL	https://www.aap.org/en-us/Pages/Default.aspx

Background:

Behavioral and emotional problems during childhood are common, often undetected, and frequently not treated despite being responsible for significant morbidity and mortality. By current estimates, approximately 11% to 20% of children in the United States have a behavioral or emotional disorder at any given time.

Purpose:

Psychosocial/behavior Assessment should be done at each well child visit. This assessment should be family centered and may include an assessment of child social-emotional health, caregiver depression, and social determinants of health.

- Per AAP, social determinants of health (SDOH) are the web of interpersonal and community relationships experienced by children, parents, and families.
- Per CDC, social determinants of health (SDOH) are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality of life risks and outcomes.

Links:

- **Promoting Optimal Development: Screening for Behavioral and Emotional Problems**
  https://pediatrics.aappublications.org/content/135/2/384
- **Bright Futures Tool and Resource Kit, 2nd Edition**
  https://toolkits.solutions.aap.org/bright-futures/home
- **Poverty and Child Health in the United States**
  https://publications.aap.org/pediatrics/article/137/4/e20160339/81482/Poverty-and-Child-Health-in-the-United-States
- **Integrating Social Determinants of Health Into Health Supervision Visits**
  https://brightfutures.aap.org/Bright%20Futures%20Documents/BF_IntegrateSDoH_Tipsheet.pdf
- **About Social Determinants of Health (CDC)**
  https://www.cdc.gov/socialdeterminants/about.html

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SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) & Behavioral Health Treatment (BHT) Coverage for Medi-Cal Members under the Age of 21
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	DHCS APL 19-010 and DHCS APL 19-014
Agency/Organization Source:	Department of Health Care Services
Agency/Organization URL	https://www.dhcs.ca.gov/services/Pages/EPSDT.aspx

Background:

The Department of Health Care Services (DHCS) and the Department of Managed Health Care (DMHC) published a number of new requirements in 2020.

Responsibilities:

- Ensure appropriate authorization of services for eligible Medi-Cal members.
- Ensure that the definition of medical necessity aligns with the APL.
- Use the current AAP/Bright Futures periodicity schedule and guidelines for the provision of services.
- Ensure BHT services are provided by the appropriate provider.
- Ensure that behavioral treatment plans are reviewed, revised, and/or modified at least every six months.

Resources:

- **DHCS APL 19-010 EPSDT**
  https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2019/APL19-010.pdf
- **DHCS APL 19-014 BHT**
  https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2019/APL19-014.pdf
- **AAP Bright Futures**
  https://brightfutures.aap.org/Pages/default.aspx
- **Early and Periodic Screening, Diagnostic, and Treatment Services**
  https://www.dhcs.ca.gov/services/Pages/EPSDT.aspx
- **Recommendations for Preventive Pediatric Health Care**
  https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf

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American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

GETTING STARTED:
IMPLEMENTING A SCREENING PROCESS

The following worksheet has been created as a guide to help you in developing a *screening process* workflow for your practice. For the purposes of this worksheet, a screening process is defined as the method of early identification and intervention for potential risks to a child's development through ongoing surveillance, routine screening per AAP guidelines, family-centered discussion of results, interpretation, and—when concerns are identified—referral and follow-up.

STEP 1: Identify current screening tools. *What formal assessments are we currently using to identify concerns?*

Developmental screenings:

General developmental screening: _____

Social-emotional screening: _____

Autism screening: _____

Maternal depression screening: _____

Social determinants of health tool(s)/questions: _____

STEP 2: Identify your practice champion. *Who will lead our team through implementing or improving the screening process?*

_____

STEP 3: Identify the practice team members that will be part of the screening process. *Who is on our screening workforce team and what are their roles?*

_____
_____
_____
_____
_____
_____

STEP 4: Select the screening tool(s) and educational materials that will be used. *What fits best with our practice structure and patient population?*

Developmental screenings:

General developmental screening: _____

Social-emotional screening: _____

Autism screening: _____

Maternal depression screening: _____

Social determinants of health screening tool/questions: _____

Educational materials:

_____
_____
_____
_____

STEP 5: Plan key parts of the workflow/process for each of the screening categories. *How will we get this done?*

See Workflow Planning Worksheet on the following 2 pages.

STEP 5: Workflow planning worksheet		DEVELOPMENTAL SCREENING	SOCIAL-EMOTIONAL SCREENING	AUTISM SCREENING	MATERNAL DEPRESSION SCREENING	SOCIAL DETERMINANTS OF HEALTH SCREENING
1.)	At what ages of the child will the family receive the screenings? Recommendations:	9, 18, and 30 months	Regular intervals	18 and 24 months	1, 2, 4, and 6 months	Every visit
2.)	How will parents access the screening tool to complete it? (Ex: EMR portal, paper version in office, laminated wipe-away)					
3.)	If paper, who will ensure that copies of the screening tool are available for parents to complete each day?					
4.)	When in the visit will the parent receive the screening tool?					
5.)	Who will give the parent the screening tool?					
6.)	Who will score the screening tool?					
7.)	When will the provider review the screening results with the parent and work with them to make a plan for next steps?					
8.)	How will referrals be handled for children at risk?					

STEP 5: Workflow planning worksheet		DEVELOPMENTAL SCREENING	SOCIAL-EMOTIONAL SCREENING	AUTISM SCREENING	MATERNAL DEPRESSION SCREENING	SOCIAL DETERMINANTS OF HEALTH SCREENING
9.)	Who will be responsible for facilitating the referrals?					
10.)	Where will referrals be documented?					
11.)	What happens with the screening tool after it has been discussed with the parent? (Ex: results recorded in EMR, scanned into chart, shredded, wiped away)					
12.)	Who will give the parent educational materials? When will these be presented?					
13.)	Where will you keep your supply of educational materials?					
14.)	Who will make sure that materials (including screening tools and educational materials) are restocked and readily available?					
15.)	Who will facilitate following up with families to determine the outcomes of the referral?					
16.)	Where will follow-up notes be recorded?					

STEP 6: Identify program supports. *What partners can we work with to support our patients? What materials do we need for our process?*

RESOURCES FOR DEVELOPMENTAL CONCERNS

Local care coordination service program for children: _____

State Early Intervention services: _____

Developmental behavioral pediatrician: _____

Speech therapist: _____

Occupational therapist: _____

Physical therapist: _____

Child Care Resource and Referral Agency (CCR&R): _____

Child Care Health Consultants: _____

Infant Mental Health Consultants: _____

Head Start: _____

Parents as Teachers: _____

School system preschool coordinator: _____

Local early childhood collaboration: _____

Local family support group: _____

School nurse contact: _____

Exceptional child contact (school system): _____

State/Local education office: _____

Local Easter Seals: _____

Local The Arc: _____

School United Way: _____

MENTAL HEALTH RESOURCES

Maternal depression: _____

Local services identified by Postpartum Support International: _____

Local new moms group: _____

Parental/Caregiver depression: _____

Child psychologist: _____

Child behavioral therapist: _____

Substance use support: _____

Domestic violence support: _____

Additional Resources:

Postpartum Progress
National Alliance on Mental Illness
800-950-NAMI (6264)
National Institute of Mental Health
National Suicide Prevention Lifeline
1-800-273-TALK (8255) or Live Online Chat
Substance and Mental Health Services Administration
SAMHSA Treatment Referral Helpline – 1-877-SAMHSA7 (1-877-726-4727)

FAMILY SUPPORT RESOURCES

State/Local health department: _____

Local home visiting program identified by the Maternal and Child Health Bureau: _____

Parenting groups: _____

Local food pantries listed on Feeding America website: _____

Local homeless shelter: _____

Local contact information for Public Housing Authority programs: _____

Supplemental Nutrition Assistance Program (food stamps): _____

Women, Infants, and Children (WIC) services: _____

National Diaper Network: _____

Local homelessness prevention provider: _____

State/Local legal services agency: _____

STEP 7: Engaging staff in the concepts, principles and process.

How will you work with staff to develop the process? How will new staff receive initial training on the concepts? How will staff be refreshed/reminded of this information?

_____
_____
_____

How will the team monitor progress and make changes as necessary? Will there be regular forums for feedback? Is there a structure to how feedback is presented?

_____
_____
_____

ACKNOWLEDGEMENTS:
This resource was adapted from a version developed by the North Carolina Assuring Better Child Health and Development program.

SAN FRANCISCO HEALTH PLAN
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Resource Guide

Subject:	Depression Screening
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	AB 2193 (Chapter 755, Statutes of 2018) Health and Safety Code, section 123640
Agency/Organization Source:	US Preventive Service Task Force (USPSTF)/American Academy of Family Physician AAFP
Agency/Organization URL	https://www.uspreventiveservicestaskforce.org/ https://www.aafp.org/home.html

Background:

Primary care physicians are well situated to discuss risks and offer interventions. Evidence supports routinely screening for obesity and depression, offering testing for human immunodeficiency virus infection, and screening for other sexually transmitted infections in some adolescents.

It is estimated that postpartum depression (PPD) affects approximately 1 in 9 new mothers in the US annually. Unaddressed PPD can have harmful, long-term effects on mothers, their babies, and their family members.

DHCS Standard:

Pediatric Depression Screening

- AAP recommends screening for major depressive disorder (MDD) in adolescents aged 12 to 20 years.
- Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up if screening is positive and a follow up plan is documented.
- Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening is positive for depression.
- Depression screening must be done using a validated screening tool.

Maternal Depression Screening

- Maternal mental health condition is defined as a mental health condition that occurs during pregnancy or during the postpartum period and includes, but is not limited to, postpartum depression.
- Maternal depression screen at 1-, 2-, 4-, and 6-month visits.
- Maternal depression screening must be done using a validated screening tool, such as the Edinburgh Postnatal Depression Scale (EPDS), Postpartum Depression Screening Scale, or Patient Health Questionnaire (PHQ) 9.
- As with any screening test, results should be interpreted within the clinical context and when appropriate referral to the PCP and/or to mental health care providers for follow up.

- Provider shall offer and document appropriate follow-up intervention(s) for women whose screening is positive for maternal depression.

Purpose:

The PHQ-2, comprising the first 2 items of the PHQ-9, inquiries about the degree to which an individual has experienced depressed mood and anhedonia over the past two weeks. Its purpose is not to establish final diagnosis or to monitor depression severity, but rather to screen for depression. Patients who screen positive should be further evaluated with the PHQ-9 to determine whether they meet criteria for a depressive disorder. The PHQ-2 has been validated in 3 studies in which it showed wide variability in sensitivity (Gilbody, Richards, Brealey, and Hweitt, 2007).

Links:

- **Mental Health Tools for Pediatrics**
  https://downloads.aap.org/AAP/PDF/Mental_Health_Tools_for_Pediatrics.pdf
- **American College of Obstetricians and Gynecologists (ACOG) guidance on Screening for Perinatal Depression**
  https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/11/screening-for-perinatal-depression
- **Incorporating Recognition and Management of Perinatal and Postpartum Depression into Pediatric Practice**
  https://pediatrics.aappublications.org/content/143/1/e20183259
- **ACOG Frequently Asked Questions on Postpartum Depression**
  https://www.acog.org/Patients/FAQs/Postpartum-Depression
- **USPSTF recommendation on Screening Depression in Adults**
  https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/depression-in-adults-screening1
- **U.S. Department of Health and Human Services guidance on Postpartum Depression**
  https://www.womenshealth.gov/mental-health/mental-health-conditions/postpartum-depression
- **Adolescent Health Screening and Counseling**
  https://www.aafp.org/afp/2012/1215/p1109.html

SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Drug Use Disorder Screening and Behavioral Counseling (Pediatric and Adult)		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or superseding APL APL 21-014 or any superseding APL for details on Alcohol and Drug Screening, Assessment, Brief Interventions and Referral to Treatment.		

Purpose:

Provider shall screen individuals 11 years and older for drug use disorders. Provider shall offer and document appropriate follow-up interventions for patient whose screening reveals unhealthy drug use.

Definition:

Unhealthy drug use: the use of illegally obtained substances, excluding alcohol and tobacco, or the use of non-medical prescription medications that differ than the parameters for which they were prescribed such as duration, frequency, and amount.

Policy:

Per AAP recommendations, drug use screening and behavioral counseling should begin at 11 years of age.

Provider shall offer and document appropriate follow-up interventions for patient whose screening reveals unhealthy drug use.

Assess all adults at each well visit for drug misuse.

Procedure:

For Pediatric Members

1. Conduct risk assessment/screening for drug use for members beginning at age 11 using a validated drug assessment tool, such as CRAFFT.

1. CRAFFT is a validated substance screening tool for adolescents aged 12-21

2. If screening is positive

    1. Validated tools should be used to determine if unhealthy drug use is present

3. If brief assessments reveal unhealthy drug use, brief misuse, counseling with appropriate referral for additional evaluation and treatment options, referrals, or services must be offered.

4. Brief interventions must include the following:

    • Providing feedback to the patient regarding screening and assessment results;

    • Discussing negative consequences that have occurred and the overall severity of the problem;

    • Supporting the patient in making behavioral changes; and

    • Discussing and agreeing on plans for follow-up with the patient, including referral to other treatment if indicated.

<u>For Adult Members</u>

1. Conduct risk assessment/screening (i.e. IHEBA)

2. If screening is positive

    1. Refer any member identified with possible drug use disorders to the drug treatment program in the county where the member resides for evaluation and treatment.

    2. Complete at least one expanded screening, using a validated screening tool, every year and additional screenings can be provided in a calendar year if medical necessity is documented by the member's provider.

        1. Validated assessment tools include, but are not limited to:

            1. CRAFFT (Car, Relax, Alone, Forget, Friends, Trouble)

            2. NIDA-modified Alcohol, Smoking, and Substance Involvement Screening Test (NM-ASSIST)

            3. Drug Abuse Screening Test (DAST-20)

    3. Offer behavioral counseling intervention(s) to those members that a provider identified as having as having risky or hazardous drug use.

        1. Behavioral counseling intervention(s) typically include one to three sessions, 15 minutes in duration per session, offered in-person, by telephone, or by telehealth modalities.

        2. Brief interventions must include the following:

            1. Providing feedback to the patient regarding screening and assessment of results.

            2. Discussing negative consequences that have occurred and the overall severity of the problem.

            3. Supporting the patient in making behavioral changes.

            4. Discussing and agreeing on plans for follow-up with the patient, including referral to other treatment if indicated.

4. Appropriate referral for additional evaluation and treatment, including medications for addiction treatment (MAT), should be offered to recipients whose brief assessment demonstrates probable substance use disorder.

3. Documentation Requirements

Member medical records must include the following:

1. The service provided, for example: screen and brief intervention.
2. The name of the screening instrument and the score on the screening instrument (unless the screening tool is embedded in the electric health record).
3. The name of the assessment instrument (when indicated) and the score on the assessment (unless the screening tool is embedded in the electronic health record).
4. If and where a referral to an alcohol or substance use disorder program was made

Resources:

CRAFFT
http://crafft.org/

AAP guidance on Substance Use Screening, Brief Intervention, and Referral to Treatment
https://pediatrics.aappublications.org/content/138/1/e20161211

_____ _____
First Name Last Name – Title Date

_____ _____
First Name Last Name – Title Date

Blood Lead Screening

Print Child's Full name: _____

Child's Date of Birth: _____**MRN:** _____

Risk Assessment & Screening

Ask: "Does your child live in, or spend a lot of time in, a place built before 1978 that has peeling or chipped paint or that has been recently remodeled?"

☐ **No suspected lead exposure** _____/_____/_____

☐ **Anticipatory Guidance given** (MM/DD/YYYY)

Blood lead test: If the answer to the question is "yes" or "don't know."

Other indications for blood lead test

☐ ***Suspected lead exposure***

☐ ***Parental request***

☐ ***Recent immigrant from country with high levels of environmental lead***

☐ ***Change in circumstance has put child at risk of lead exposure***

Received a ☐ Venous / ☐ Capillary blood lead test on _____/_____/_____
(MM/DD/YYYY)

Test was administered by: _____
(Signature of HealthCare Professional)

Parent/Guardian Refusal of Blood Lead Testing

I verify that I have been made aware of the serious and long-term health effects of lead poisoning on children under the age of six years. I do object to my child being blood tested in order to determine if he/she is lead poisoned, and hereby refuse blood lead testing. I am aware that a copy of this refusal will be documented in my child's medical record.

Reason for Refusal _____

Signature _____**Relation to child**_____ **Date**_____/_____/_____
(parent or guardian) (MM/DD/YYYY)

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Policy and Procedure

Policy Name:	Dental/Oral Health Assessment, Fluoride Supplementation, and Fluoride Varnish		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

The provider is responsible for ensuring that dental screening/oral health assessment for all members are included as part of the initial health assessment (IHA) and at each subsequent pediatric health assessment visit. This multi-part assessment may include a physical examination, application of fluoride varnish, prescription of fluoride supplementation, and referral to a dental home.

Definition:

Dental Home: The American Academy of Pediatric Dentistry (AAPD) supports the concept of a dental home for all infants, children, adolescents, and persons with special health care needs. The AAPD encourages parents and other care providers to help every child establish a dental home. Every child should have a dental home established by 12 months of age.

Fluoride Varnish is a dental treatment that can help prevent tooth decay, slow it down, or stop it from getting worse. Fluoride varnish is made with fluoride, a mineral that can strengthen tooth enamel (outer coating on teeth). Once teeth are present, fluoride varnish may be applied to all children every 3-6 months in the primary care or dental office.

Community water fluoridation is the process of adjusting the fluoride content of fluoride-deficient water to the recommended level for optimal dental health, which is currently recommended at 0.7 parts fluoride per million parts water (Source).

Policy:

Dental assessment is to be performed at every pediatric health assessment visit. This multi-part assessment may include a physical examination, application of fluoride varnish, prescription of fluoride supplementation, and referral to a dental home.

Procedure:

1. Inspection of the mouth, teeth and gums is performed at every health assessment visit.
    a. Documentation of "HEENT" is acceptable. Once teeth are present, fluoride varnish may be applied to all children every 3-6 months in the primary care or dental office.

   b. Children are referred to a dentist at any age if a dental problem is detected or suspected. Beginning at 3 years of age, all children are referred annually to a dentist regardless of whether a dental problem is detected or suspected.
2. Fluoride supplements may be prescribed for children ages 6 months to 5 years who are at high risk for tooth decay and whose primary drinking water has a low fluoride concentration.
   a. Parent(s) or legal guardian(s) should be encouraged to check with local water utility agency to verify that their tap water has fluoride.
   b. If local water does not contain fluoride, provider may recommend the purchase of fluoridated water or give prescription for fluoride drops or tablets.
3. Fluoride varnish may be applied to the teeth of infants and children starting at tooth eruption until their fifth-year birthdate.
   a. All children in this category should receive fluoride varnish application at least once every 3-6 months in the primary care or dental office.
4. If fluoride varnish is applied at dentist office, provider must document that in the medical record since not all dentists routinely apply fluoride varnish during routine dental visits

_____ _____

First Name Last Name – Title Date

_____ _____

First Name Last Name – Title Date

Resources

- Caries-risk Assessment and Management for Infants, Children, and Adolescents https://www.aapd.org/media/Policies_Guidelines/BP_CariesRiskAssessment.pdf
- AAP guidance on Fluoride Use in Caries Prevention in the Primary Care Setting http://pediatrics.aappublications.org/content/134/3/626
- AAP Oral Health Practice Tools https://www.aap.org/en/patient-care/oral-health/oral-health-practice-tools/.
- My Water's Fluoride https://nccd.cdc.gov/doh_mwf/default/default.aspx
- Maintaining and Improving the Oral Health of Young Children http://pediatrics.aappublications.org/content/134/6/1224.
- USPSTF guidance on Dental Caries in Children Younger Than 5 Years https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-dental-caries-in-children-younger-than-age-5-years-screening-and-interventions1
- Guidance on Fluoride Supplementation https://publichealth.nc.gov/oralhealth/library/includes/IMBresources/2020-FluorideSupplementation.pdf#:~:text=Pediatric%20Dentistry%20%28AAPD%29%20recommend%20the%20daily%20administration%20of,years%20of%20age%20to%20provide%20the%20maximum%20benefits

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SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Tuberculosis Screening – Pediatric and Adult		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:			
Facility Site Review Source:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Background:

Tuberculosis is a potentially fatal contagious disease that can affect almost any part of the body but is mainly an infection of the lungs. It is caused by a bacterial microorganism, the tubercle bacillus or Mycobacterium tuberculosis.

Tuberculosis disease was once the leading cause of death in the United States. Today, however, people with active TB disease can be treated and cured if they seek medical help. Even better, people with latent TB infection can take medicine so they will not develop active TB disease.

Purpose:

Tuberculosis ITB) Risk Assessment is an activity to assess and document a patient's TB symptoms and/or risk factors. A completed risk assessment form and/or screening practices will help the provider to determine the need for further medical testing and evaluation.

Policy:

1. Tuberculosis screening is required for all new members unless it was done in the past year.
2. Tuberculosis screening is completed at each health assessment visit.
3. Providers are required to follow current CDC and American Thoracic Society guidelines for TB diagnosis and treatment.

Procedure:

1. Pediatrics
    a. All children are assessed for risk of exposure to tuberculosis (TB) at 1, 6, and 12- months old and annually thereafter at each health assessment.

b. The Mantoux skin test, or other approved TB infection screening test, is administered to children *identified at risk,* if there has not been a test in the previous year. The Mantoux is not given if a previously positive Mantoux is documented.
c. Documentation of a positive test includes follow-up care (e.g. further medical evaluation, chest x-ray, diagnostic laboratory studies and/or referral to specialist).
d. Two tests that are used to detect TB bacteria in the body: the TB skin test (TST) (Mantoux) and TB blood tests QuantiFERON-TB Gold Plus.
    i. A positive TB skin test or TB blood test only tells that a person has been infected with TB bacteria.
    ii. TB infection screening test is administered to children identified at risk if there has not been a test in the previous year.
e. The Mantoux is not given if a previously positive Mantoux is documented.
    i. Documentation of a positive test includes follow-up care
        1. Further medical evaluation
        2. Chest X-Ray
        3. Diagnostic laboratory studies
        4. Referral to Specialist

2. Adults
    a. All adults are screened for tuberculosis (TB) risk factors upon enrollment and at periodic physical evaluations.
    b. The Mantoux skin test, or other approved TB infection screening test, is administered to all asymptomatic persons at increased risk of developing TB irrespective of age or periodicity if they had not had a test in the previous year.
    c. Adults already known to have HIV or who are significantly immunosuppressed require annual TB testing.
    d. The Mantoux is not given if a previously positive Mantoux is documented.
        i. Documentation of a positive test includes follow-up care
            1. Further medical evaluation
            2. Chest X-Ray
            3. Diagnostic laboratory studies
            4. Referral to Specialist

Resources:

- **CDC TB Publications & Products**
- https://www.cdc.gov/tb/publications/
- **CDPH Pediatric TB Risk Assessment**
  https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB-CA-Pediatric-TB-Risk-Assessment.pdf
- **CDPH Adult TB Risk Assessment**
  https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB-CA-TB-Risk-Assessment-and-Fact-Sheet.pdf
- **USPSTF recommendation on Latent TB Infection Screening**
  https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/latent-tuberculosis-infection-screening

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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.

California Pediatric Tuberculosis Risk Assessment

- Use this tool to identify asymptomatic **children** for latent TB infection (LTBI) testing.
- **Do not repeat testing** unless there are **new risk factors** since the last test.
  If initial negative screening test occurred prior to 6 months of age, repeat testing should occur at age 6 months or older
- Do not treat for LTBI until active TB disease has been excluded:
  For children with TB symptoms or abnormal chest x-ray consistent with active TB disease, evaluate for active TB disease with a chest x-ray, symptom screen, and if indicated, sputum AFB smears, cultures and nucleic acid amplification testing. A negative tuberculin skin test or interferon gamma release assay does not rule out active TB disease.

LTBI testing is recommended if any of the boxes below are checked.

☐ **Birth, travel, or residence** in a country with an elevated TB rate for at least 1 month

- Includes any country other than the United States, Canada, Australia, New Zealand, or a country in western or northern Europe
- If resources require prioritization within this group, prioritize patients with at least one medical risk for progression (see the California Adult Tuberculosis Risk Assessment User Guide for this list).
- Interferon Gamma Release Assay is preferred over Tuberculin Skin Test for non-U.S.-born persons ≥2 years old

☐ **Immunosuppression,** current or planned

HIV infection, organ transplant recipient, treated with TNF-alpha antagonist (e.g., infliximab, etanercept, others), steroids (equivalent of prednisone ≥2 mg/kg/day, or ≥15 mg/day for ≥2 weeks) or other immunosuppressive medication

☐ **Close contact** to someone with infectious TB disease during lifetime

Treat for LTBI if LTBI test result is positive and active TB disease is ruled out.

☐ **None**; no TB testing is indicated at this time.

Provider Name: _____

Assessment Date: _____

Patient Name: _____

Date of Birth: _____

See the California Pediatric TB Risk Assessment User Guide for more information about using this tool. To ensure you have the most current version, go to the TB RISK ASSESSMENT page (https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Risk-Assessment.aspx)

California TB Pediatric Risk Assessment User Guide

Avoid testing persons at low risk

Routine testing of persons without risk factors is not recommended and may result in unnecessary evaluations and treatment because of falsely positive test results.

Local recommendations, mandated testing and other risk factors

Several risk factors for TB that have been used to select children for TB screening historically or in mandated programs are not included among the 3 components of this risk assessment. This is purposeful in order to focus testing on children at highest risk. However, certain populations may be mandated for testing by statute, regulation, or policy. This risk assessment does not supersede any mandated testing. Testing can also be considered in children with frequent exposure to adults at high risk of TB infection, such as those with extensive foreign travel in areas with high TB rates. Local recommendations should also be considered in testing decisions. Local TB control programs and clinics can customize this risk assessment according to local recommendations. **Providers should check with local TB control programs for local recommendations.** A directory of TB Control Programs is available on the CTCA website. (https://www.ctca.org/locations.html)

Most patients with LTBI should be treated

Persons with risk factors who test positive for LTBI should generally be treated once active TB disease has been ruled out with a physical exam, chest radiograph and, if indicated, sputum smears, cultures, and nucleic acid amplification testing (NAAT). However, clinicians should not feel compelled to treat persons who have no risk factors but have a positive test for LTBI.

When to repeat a risk assessment and testing

Risk assessments should be completed for new patients, patients thought to have new potential exposures to TB since last assessment, and during routine pediatric well-child visits. Repeat risk assessments should be based on the activities and risk factors specific to the child. Children who volunteer or work in health care settings might require annual testing and should be considered separately. Re-testing should only be done in persons who previously tested negative and have new risk factors since the last assessment (unless they were <6 months of age at the time of testing). In general, new risk factors would include new close contact with an infectious TB case or new immunosuppression, but could also include foreign travel.

Immunosuppression

The exact level of immunosuppression that predisposes to increased risk for TB progression is unknown. The threshold of steroid dose and duration used in the Pediatric TB Risk Assessment are based on data in adults and in accordance with ACIP recommendations for live vaccines in children receiving immunosuppression.

Foreign travel or residence

Travel or residence in countries with an elevated TB rate may be a risk for TB exposure in certain circumstances (e.g., extended duration, likely contact with persons with infectious TB, high prevalence of TB in travel location, non-tourist travel). The duration of at least 1 consecutive month to trigger testing is intended to identify travel most likely to involve TB exposure. TB screening tests can be falsely negative within the 8 weeks after exposure, so are best obtained 8 weeks after a child's return.

IGRA preference in non-U.S.-born children ≥2 years old

Because IGRA has increased specificity for TB infection in children vaccinated with BCG, IGRA is preferred over the tuberculin skin test for non-U.S.-born children ≥2 years of age. IGRAs can be used in children <2 years of age, however, there is an overall lack of data in this age group, which complicates interpretation of test results. In BCG vaccinated immunocompetent children with a positive TST, it may be appropriate to confirm a positive TST with an IGRA. If IGRA is not done the TST result should be considered the definitive result.

Negative test for LTBI does not rule out active TB

It is important to remember that a negative TST or IGRA result does not rule out active TB disease. A negative TST or IGRA in a patient with active TB disease can be a sign of extensive disease. Any suspicion for active TB disease or extensive exposure to TB should prompt an evaluation for active TB disease, including physical exam, symptom review, and 2-view chest x-ray.

Emphasis on short course for treatment of LTBI

Shorter regimens for treating latent TB infection have been shown to be as effective as 9 months of isoniazid, and are more likely to be completed. Use of these shorter regimens is preferred in most patients, although the 12 week regimen is not recommended for children <2 years of age or children on antiretroviral medications. It is under study in pregnancy. Drug- drug interactions and contact to drug resistant TB are other contra-indications for shorter regimens.

Shorter duration LTBI treatment regimens

Medication	Frequency	Duration
Rifampin	Daily	4 months
Isoniazid + rifapentine	Weekly	12 weeks*

* 11-12 doses in 16 weeks required for completion.

Refusal of recommended LTBI treatment

Refusal should be documented. Recommendations for treatment should be made at future encounters with medical services. If treatment is later accepted, TB disease should be excluded and chest x-ray repeated if it has been more than 6 months from the initial evaluation for children 5 years or older and 3 months for children less than 5 years of age.

Symptoms that should trigger evaluation for active TB

Patients with any of the following symptoms that are otherwise unexplained should be evaluated for active TB disease: cough for more than 2-3 weeks, fevers, night sweats, weight loss, lymphadenopathy, hemoptysis or excessive fatigue.

Resources

Fact Sheets for LTBI Regimens, Isoniazid+Rifapentine, Rifampin, and Isoniazid are available on the TBCB LTBI Treatment page. (www.cdph.ca.gov/LTBITreatment)

American Academy of Pediatrics, Red Book Online, Tuberculosis is available on the Red Book Online website. (https://redbook.solutions.aap.org/chapter.aspx?sectionid=189640207&bookid=2205)

Abbreviations

AFB= acid-fast bacilli BCG= Bacillus Calmette-Guérin
CXR= chest x-ray DOT= directly observed therapy
IGRA=interferon gamma release assay LTBI= latent TB infection
MDR =multiple drug resistant NAAT= nucleic acid amplification testing
SAT= self-administered therapy TST= tuberculin skin test

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Vision Screening		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

Age-appropriate visual screening occurs at each health assessment visit, with referral to optometrist/ophthalmologist as appropriate. A visual acuity screen is recommended at ages 4 and 5 years, as well as in cooperative 3-year-olds. Instrument-based screening may be used to assess risk at ages 12 and 24 months, in addition to the well visits at 3 through 5 years of age. Documentation of "PERRLA" is acceptable for children below the age of 3 years.

Procedure:

1. Vision screenings will be performed according to American Academy of Pediatrics/ Bright Futures Recommendations for Preventive Pediatric Health Care or medically necessary.
   a. Vision screenings are not recommended for most healthy adults, but adults are encouraged to get regular eye exams from an eye care specialist
2. Screening for infants and children (birth to 3 years):
   a. External eye inspection, ophthalmoscopy red reflex examination, or corneal penlight evaluation.
3. Visual acuity screening begins at age 3

Using Snellen Eye Chart:

1. Place the chart on a wall or easel 10/20 feet away.
2. Cover one eye with an occluder, completely blocking the vision of the covered eye. (Do not apply pressure to the covered eye, as it might affect that eye's vision when you test it.)
3. Have patient identify a line on the chart that he/she can comfortably read.
4. Have patient continue trying to read the letters on each successively smaller line. Do not squint.
5. Stop screening when patient fails to correctly identify at least 50 percent of the letters on a line.
6. Switch to the other eye and repeat.

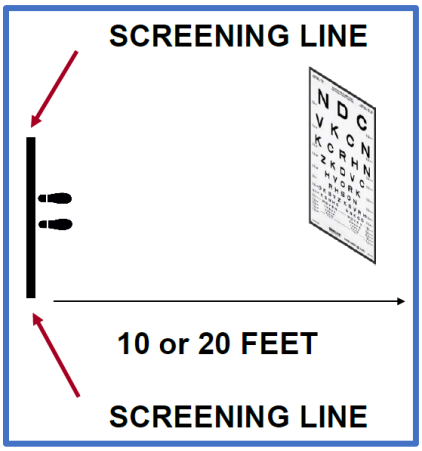
Record visual acuity for each eye by noting the line for which you correctly identified either:

a) More than half the letters on that line, but not all of them.

b) All letters on that line, plus a few letters (less than half) on the next line.

AAP recommended eye charts are:

1. LEA Symbols (3-5 years old)
2. HOTV Chart (3-5 years old)
3. Sloan Letters (preferred) or Snellen Letters (over 5 years old)



Resources:

1. Bright Futures/AAP Recommendations for Preventive Pediatric Health Care (Periodicity Schedule)
2. CHDP Pediatric Vision Training
3. Snellen Eye Chart
4. MedlinePlus: Vision Screening

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SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Childhood Immunizations		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL APL 18-004, Immunization Requirements, or any superseding APL for details on Immunization Requirements National Childhood Vaccine Injury Act		

Purpose:

On-time vaccination throughout childhood is essential because it helps provide immunity before children are exposed to potentially life-threatening diseases. Vaccines are tested to ensure that they are safe and effective for children to receive at the recommended ages. CDC recommends all children receive vaccines according to the recommended immunization schedule to protect them from 14 diseases by age two.

Policy:

Immunization status is assessed at each health assessment visit. Providers are required to ensure the provision of immunizations according to CDC's most recent Advisory Committee on Immunization Practices (ACIP) guidelines, unless medically contraindicated, vaccine shortage or refused by the parent.

Procedure:

1. Assess immunization status at each health assessment visit.
2. Ensure provision of immunizations according to ACIP guidelines unless medically contraindicated, vaccine shortage or refused by the parent.
    a. Check up to date vaccination status
    b. Check local immunization information system
    c. Screen for contraindications and precautions
3. Appropriately document each vaccine administration by including the following information in the member's medical record:
    a. Date of administration

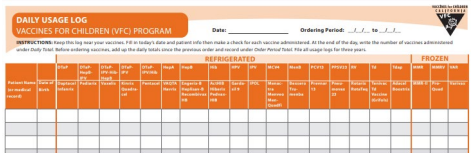
b. Vaccine manufacturer
c. Vaccine lot number
d. Name and title of the person who administered the vaccine and address of the facility where the permanent record will reside
e. Vaccine information statement (VIS) date printed on the VIS
f. Date the VIS was given to the member or parent/guardian

4. Document any parental declinations, vaccine shortages, medical contraindications, or adverse reaction in the member's Medical Record.

Resources:

- **ACIP Vaccine Recommendations and Guidelines**
  https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- **Immunization Schedule for Children and Adolescents 18 years or younger**
  https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
- **Screening checklist for contraindications to vaccines for children and teens**
  https://www.immunize.org/catg.d/p4060.pdf
- **CDC Resources for Health Care Providers**
  https://www.cdc.gov/vaccines/schedules/hcp/resources.html
  California Immunization Registry Website
  https://cair.cdph.ca.gov/CAPRD/portalInfoManager.do
- **Vaccine Administration Record for Children and Teens**
  https://immunize.org/catg.d/p2022.pdf
- **Vaccine Administration Record for Adults**
  https://immunize.org/catg.d/p2023.pdf

- **EZIZ Vaccine Management – Daily Usage Log/ Flu Usage Log**
  https://eziz.org/vaccine-management/


DAILY USAGE LOG
VACCINES FOR CHILDREN (VFC) PROGRAM
Date: _____ Ordering Period: __/__/__ to __/__/__
INSTRUCTIONS: Keep this log near your vaccines. Fill in today's date and patient info then make a check for each vaccine administered. At the end of the day, write the number of vaccines administered under Daily Total. Before ordering vaccines, add up the daily totals since the previous order and record under Order Period Total. File all usage logs for three years.
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FROZEN

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SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Depression Screening (General Adult Population), including Pregnant and Postpartum Women		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or superseding APL AB 2193 (Chapter 755, Statutes of 2018) Health and Safety Code, section 123640		

Purpose:

Per USPSTF, screen for depression in the general adult population, including pregnant and postpartum women. Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.

Definition:

Policy:

1. Screening should be implemented at each well visit with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.
2. Providers should screen all adults who have not been previously screened using a validated screening tool. If the depression screening is positive, a follow up plan must be documented.
3. Providers should use clinical judgment in consideration of risk factors, comorbid conditions, and life events to determine if additional screening of high-risk patients is warranted

Procedure:

1. Screen adults for depression at each well visit using a validated screening tool

1. The IHEBA forms when used solely for depression screening do not have psychometric properties and may not be reliable screening tools for depression.

2. *Recommended screening tools:*

    1. Patient Health Questionnaire (PHQ) in various forms

    2. Hospital Anxiety and Depression Scales in adults

    3. Geriatric Depression Scale in older adults

    4. The Edinburgh Postnatal Depression Scale (EPDS) pregnant and postpartum

2. If screening is positive

    1. All positive screening results should lead to additional assessment that considers severity of depression and comorbid psychological problems (eg, anxiety, panic attacks, or substance abuse), alternate diagnoses, and medical conditions.

    2. Provider must document a follow up plan

Resources:

USPSTF recommendation on Screening for Depression in Adults
https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/depression-inadults-screening

American College of Obstetricians and Gynecologists (ACOG) guidance on Screening for Perinatal Depression,
https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/11/screening-for-perinatal-depression

Incorporating Recognition and Management of Perinatal and Postpartum Depression into Pediatric Practice
https://pediatrics.aappublications.org/content/143/1/e20183259

ACOG Frequently Asked Questions on Postpartum Depression
https://www.acog.org/Patients/FAQs/Postpartum-Depression

USPSTF recommendation on Screening Depression in Adults
https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/depression-in-adults-screening

U.S. Department of Health and Human Services guidance on Postpartum Depression
https://www.womenshealth.gov/mental-health/mental-healthconditions/postpartum-depression

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First Name Last Name – Title Date

SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Folic Acid Supplementation		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL		

Purpose:

All women planning or capable of pregnancy should get 0.4 to 0.8 mg (400 to 800µg) of folic acid each day, in addition to consuming food with folate from a varied diet, to help prevent neural tube defects (NTDs).

Definition:

Neural Tube Defects: Major birth defects of the baby's brain (anencephaly) and spine (spina bifida).

Folic Acid (Folate): One of the B vitamins (B9) that is a key factor in the synthesis (the making) of nucleic acid (DNA and RNA). Lack of adequate folic acid during pregnancy was first found to increase the risk for the baby to have a birth defect involving the spinal cord and brain -- a neural tube defect such as spina bifida (meningomyelocele) or anencephaly.

"Capable of Pregnancy":

USPSTF and WHO categorize women in the age range of 12-49 years as "women who are capable of becoming pregnant".

The average woman's reproductive years are between ages 12 and 51. Per Planned Parenthood, pregnancy is possible as soon as a girl begins ovulating or producing eggs. A girl's first ovulation will happen about 14 days before their first menstrual period. This means that a young girl can become pregnant from vaginal intercourse before her first period. This happens to some females as early as when they are eight years old, or even earlier. Most often, ovulation begins before women turn 20. On average, it first happens when a girl is between 12 and 13.

The last ovulation in a woman's life is called menopause. Menopause itself is a single point in time 12 months after a woman has her last period, according to the National Institute on Aging (NIA). Menopause can happen as early as when a woman is 40. But the average age for menopause is 51. Per ACOG (American College of Obstetricians and Gynecologists), by age 45 years, getting pregnant naturally is unlikely for most women; however, it is still possible to become pregnant during the perimenopause stage until there has been 12 months without having a period.

Policy:

All female patients planning or capable of pregnancy will receive recommendation and/or prescription for the supplementation of 0.4 to 0.8 mg (400 to 800µg) folic acid.

Procedure:

1. Assess female patients for menarche or last menstrual period.

2. Recommend and/or prescribe folic acid 0.4 to 0.8 mg (400 to 800µg) supplement to all females planning and/or capable of pregnancy.
3. Document date of menarche or last menstrual period in the Medical Record
4. Document recommendation or declination of folic acid in the Medical Record.

Resources:

Folic Acid for the Prevention of Neural Tube Defects: Preventive Medication, USPSF
https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/folic-acid-for-the-prevention-of-neural-tube-defects-preventive-medication

March of Dimes
https://www.marchofdimes.org/pregnancy/folic-acid.aspx

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SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Osteoporosis Screening		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review		

Purpose:

For women 65 years and older, the USPSTF found convincing evidence that screening can detect osteoporosis and that treatment of women with osteoporosis can provide at least a moderate benefit in preventing fractures. For postmenopausal women younger than 65 years who are at increased risk of osteoporosis, the USPSTF found adequate evidence that screening can detect osteoporosis and that treatment provides a moderate benefit in preventing fractures.

Osteoporotic fractures, particularly hip fractures, are associated with limitation of ambulation, chronic pain and disability, loss of independence, and decreased quality of life, and 21% to 30% of patients who experience a hip fracture die within 1 year.

Definitions:

Osteoporosis: Thinning of the bones, with reduction in bone mass, due to depletion of calcium and bone protein.

Bone Density Test: A bone density test is the only test that can diagnose osteoporosis before a broken bone occurs. This test helps to estimate the density of your bones and your chance of breaking a bone. NOF (National Osteoporosis Foundation) and USPSTF recommend a bone density test of the hip and spine by a central DXA machine to diagnose osteoporosis. DXA stands for dual energy x-ray absorptiometry.

Policy:

Provide osteoporosis screening with bone measurement testing to prevent osteoporotic fractures in women 65 years and older.

Provide osteoporosis screening with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal risk assessment tool (see Links)

Procedure:

1. Screen for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool
    a. Risk factors include
        i. Parental history of hip fracture
        ii. Smoking
        iii. Excessive alcohol consumption
        iv. Low body weight
2. Screen for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older.

Resources:

USPSTF: Recommendations and Screening Tools
https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/osteoporosis-screening1#tab2

Fracture Risk Assessment Tool (FRAX)
https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9

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First Name Last Name – Title Date

California Adult Tuberculosis Risk Assessment

- Use this tool to identify asymptomatic **adults** for latent TB infection (LTBI) testing.
- **Do not repeat testing** unless there are **new risk factors** since the last test.
- Do not treat for LTBI until active TB disease has been excluded:
  For patients with TB symptoms or an abnormal chest x-ray consistent with active TB disease, evaluate for active TB disease with a chest x-ray, symptom screen, and if indicated, sputum AFB smears, cultures and nucleic acid amplification testing. A negative tuberculin skin test or interferon gamma release assay does not rule out active TB disease.

LTBI testing is recommended if any of the boxes below are checked.

☐ **Birth, travel, or residence** in a country with an elevated TB rate for at least 1 month

- Includes any country other than the United States, Canada, Australia, New Zealand, or a country in western or northern Europe
- If resources require prioritization within this group, prioritize patients with at least one medical risk for progression (see the California Adult Tuberculosis Risk Assessment User Guide for this list).
- Interferon Gamma Release Assay is preferred over Tuberculin Skin Test for non-U.S.-born persons ≥2 years old

☐ **Immunosuppression,** current or planned

HIV infection, organ transplant recipient, treated with TNF-alpha antagonist (e.g., infliximab, etanercept, others), steroids (equivalent of prednisone ≥15 mg/day for ≥1 month) or other immunosuppressive medication

☐ **Close contact** to someone with infectious TB disease during lifetime

Treat for LTBI if LTBI test result is positive and active TB disease is ruled out.

☐ **None**; no TB testing is indicated at this time.

Provider Name: _____

Assessment Date: _____

Patient Name: _____

Date of Birth: _____

See the California Adult Tuberculosis Risk Assessment User Guide for more information about using this tool. To ensure you have the most current version, go to the TB RISK ASSESSMENT page (https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Risk-Assessment.aspx)

California Adult TB Risk Assessment User Guide

Avoid testing persons at low risk

Routine testing of persons without risk factors is not recommended and may result in unnecessary evaluations and treatment because of falsely positive test results.

Prioritize persons with risks for progression

If health system resources do not allow for testing of all non-U.S. born persons from a country with an elevated TB rate, prioritize patients with at least one of the following medical risks for progression:

- diabetes mellitus
- smoker within past 1 year
- end stage renal disease
- leukemia or lymphoma
- silicosis
- cancer of head or neck
- intestinal bypass/gastrectomy
- chronic malabsorption
- body mass index ≤20
- History of chest x-ray findings suggestive of previous or inactive TB (no prior treatment). Includes fibrosis or non-calcified nodules, but does not include solitary calcified nodule or isolated pleural thickening. In addition to LTBI testing, evaluate for active TB disease.

United States Preventive Services Task Force

The USPSTF has recommended testing persons born in or former residents of, a country with an elevated tuberculosis rate and persons who live in or have lived in high-risk congregate settings such as homeless shelters and correctional facilities. Because the increased risk of exposure to TB in congregate settings varies substantially by facility and local health jurisdiction, clinicians are encouraged to follow local recommendations when considering testing among persons from these congregate settings. The USPSTF did not review data supporting testing among close contacts to persons with infectious TB or among persons who are immunosuppressed because these persons are recommended to be screened by public health programs or by clinical standard of care.

Children

This risk assessment tool is intended for adults. A risk assessment tool created for use in California for children is available on the TBCB Risk Assessment page. (https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB-CA-Pediatric-TB-Risk-Assessment.pdf)

Local recommendations

Local recommendations and mandates should also be considered in testing decisions. Local TB control programs can customize this risk assessment according to local recommendations. **Providers should check with local TB control programs for local recommendations.** A directory of TB Control Programs is available on the CTCA website. (https://www.ctca.org/locations.html)

Mandated testing and other risk factors

Several risk factors for TB that have been used to select patients for TB screening historically or in mandated programs are not included among the components of this risk assessment. This is purposeful in order to focus testing on patients at highest risk. However, certain populations may be mandated for testing by statute, regulation, or policy. This risk assessment does not supersede any mandated testing. Examples of these populations include: healthcare workers, residents or employees of correctional institutions, substance abuse treatment facilities, homeless shelters, and others.

Age as a factor

Age (among adults) is not considered in this risk assessment. However, younger adults have more years of expected life during which progression from latent infection to active TB disease could develop. Some programs or clinicians may additionally prioritize testing of younger non-U.S.-born persons when all non-U.S.-born are not tested. An upper age limit for testing has not been established but could be appropriate depending on individual patient TB risks, comorbidities, and life expectancy.

Foreign travel

Travel to countries with an elevated TB rate may be a risk for TB exposure in certain circumstances (e.g., extended duration, likely contact with persons with infectious TB, high prevalence of TB in travel location, non-tourist travel). The duration of at least 1 consecutive month to trigger testing is intended to identify travel most likely to involve TB exposure. TB screening tests can be falsely negative within the 8 weeks after exposure, so are best obtained 8 weeks after return from travel.

When to repeat a test

Re-testing should only be done in persons who previously tested negative, and have new risk factors since the last assessment. In general, this would include new close contact with an infectious TB case or new immunosuppression, but could also include foreign travel in certain circumstances.

When to repeat a risk assessment

The risk assessment should be administered at least once. Persons can be screened for new risk factors at subsequent preventive health visits.

IGRA preference in BCG vaccinated

Because IGRA has increased specificity for TB infection in persons vaccinated with BCG, IGRA is preferred over the TST in these persons. Most persons born outside the United States have been vaccinated with BCG.

Previous or inactive tuberculosis

Chest radiograph findings consistent with previous or inactive TB include fibrosis or non-calcified nodules, but do not include a solitary calcified nodule or isolated pleural thickening. Persons with a previous chest radiograph showing findings consistent with previous or inactive TB should be tested for LTBI. In addition to LTBI testing, evaluate for active TB disease.

Negative test for LTBI does not rule out active TB disease

It is important to remember that a negative TST or IGRA result does not rule out active TB disease. In fact, a negative TST or IGRA in a patient with active TB disease can be a sign of extensive disease and poor outcome.

Symptoms that should trigger evaluation for active TB disease

Patients with any of the following symptoms that are otherwise unexplained should be evaluated for active TB disease: cough for more than 2-3 weeks, fevers, night sweats, weight loss, and hemoptysis.

How to evaluate for active TB disease

Evaluate for active TB disease with a chest x-ray, symptom screen, and if indicated, sputum AFB smears, cultures and nucleic acid amplification testing. A negative tuberculin skin test or interferon gamma release assay does not rule out active TB disease

Most patients with LTBI should be treated

Persons with risk factors who test positive for LTBI should generally be treated once active TB disease has been ruled out. However, clinicians should not feel compelled to treat persons who have no risk factors but have a positive test for LTBI.

Emphasis on short course for treatment of LTBI

Shorter regimens for treating latent TB infection have been shown to be as effective as 9 months of isoniazid, and are more likely to be completed. Use of these shorter regimens is preferred in most patients. Drug-drug interactions and contact to drug resistant TB are typical reasons these regimens cannot be used.

Shorter duration LTBI treatment regimens

Medication	Frequency	Duration
Rifampin	Daily	4 months
Isoniazid + rifapentine	Weekly	12 weeks*

* 11-12 doses in 16 weeks required for completion.

Patient refusal of recommended LTBI treatment

Refusal should be documented. Recommendations for treatment should be made at future encounters with medical services. If treatment is later accepted, TB disease should be excluded and CXR repeated if it has been more than 6 months from the initial evaluation; or more than 3 months if there is immunosuppression, or the prior CXR was abnormal and consistent with potentially active TB disease.

Resources

Fact Sheets for LTBI Regimens, Isoniazid+Rifapentine, Rifampin, and Isoniazid are available on the TBCB LTBI Treatment page. (www.cdph.ca.gov/LTBITreatment)

U.S. Preventive Services Task Force Latent TB Infection Screening Recommendations are available on the U.S. Preventive Services Task Force website. (https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/latent-tuberculosis-infection-screening)

Abbreviations

AFB= acid-fast bacilli BCG= Bacillus Calmette-Guérin
CXR= chest x-ray DOT= directly observed therapy
IGRA=interferon gamma release assay LTBI= latent TB infection
MDR =multiple drug resistant NAAT= nucleic acid amplification testing
SAT= self-administered therapy TST= tuberculin skin test

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Policy and Procedure

Policy Name:	Adult Immunizations		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL APL 18-004, Immunization Requirements, or any superseding APL for details on Immunization Requirements DHCS, Adult Immunizations as A Pharmacy Benefit, All Plan Letter 16-009 (Revised) National Childhood Vaccine Injury Act		

Policy:

Immunization status is assessed at periodic health evaluations. Practitioners are required to ensure the provision of immunizations according to CDC's most recent ACIP guidelines, unless medically contraindicated or refused by the member.

Procedure:

A. Providers must ensure timely provision of immunizations to patients in accordance with the most recent schedule and recommendations published by ACIP, regardless of a member's age, sex, or medical condition, including pregnancy, unless medically contraindicated or refused by the member.
B. Providers must document each member's need for ACIP recommended immunizations as part of all regular health visits, including, but not limited to the following types of encounters:
    - Illness, care management, or follow-up appointments
    - Initial Health Assessments (IHAs)
    - Pharmacy services
    - Prenatal and postpartum care
    - Pre-travel visits
    - Sports, school, or work physicals
    - Visits to a local health department (LHD)
    - Well patient checkups
C. Vaccination status must be assessed for the following:

- Td/Tdap (every 10 years),
- Flu (annually),
- Pneumococcal (starting at age 65),
- Zoster (starting at age 50),
- Varicella and MMR.
    i. Documented evidence of immunity (i.e. titers, childhood acquired infection) in the medical record meets the criteria for Varicella and MMR.

D. Documentation of immunizations, either recorded in the medical/electronic record or on medication logs, must include the following:
- The name of the vaccine(s),
- the date of administration,
- the manufacturer,
- the lot number of each vaccine,
- including immunization registries,
- the date the VIS was given (or presented and offered),
- and the VIS publication date.

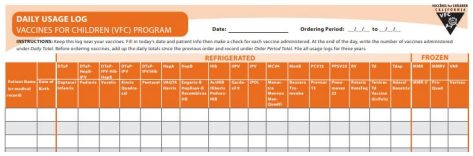
E. As ACIP-recommended, immunizations are viewed as preventive services, these services must not be subject to prior authorization. In instances where the Medi-Cal Provider Manual outlines immunization criteria that is less restrictive than ACIP criteria, MCPs must provide the immunization in accordance with the less restrictive Medi-Cal Provider Manual criteria.

F. Title 16, California Code of Regulations (CCR), Section 1746.4(e) requires pharmacists to report the administration of any vaccine, within 14 days, to the appropriate immunization registry. In addition, DHCS strongly recommends that not only pharmacists, but <u>all</u> network primary care providers, report immunization information within 14 days of administering an immunization.
- Reports to The California Immunization Registry (CAIR2)] shall be made following the member's initial health assessment and all other health care visits which result in an immunization being provided, in accordance with state and federal laws.

Resources:

- **ACIP Vaccine Recommendations and Guidelines**
  https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- **CDC Resources for Health Care Providers**
  https://www.cdc.gov/vaccines/schedules/hcp/resources.html
- **Adult Immunization Schedule**
  https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
- **California Immunization Registry Website**
  https://cair.cdph.ca.gov/CAPRD/portalInfoManager.do
- **Vaccine Administration Record for Adults**
  https://immunize.org/catg.d/p2023.pdf

- **EZIZ Vaccine Management – Daily Usage Log/ Flu Usage Log**
  https://eziz.org/vaccine-management/


DAILY USAGE LOG
VACCINES FOR CHILDREN (VFC) PROGRAM

_____	_____
First Name Last Name – Title	Date
_____	_____
First Name Last Name – Title	Date

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