### Full Scope OB Site Review Survey 2012

California Department of Health Care Services

Medi-Cal Managed Care Division

Health Plan: PHC	I	IPA:				Site ID No:		Review D	Date:	Fire Clearance Current? Y/N
Provider Name:	l.							Phone:		Fax:
Provider Address:						Contact Persor	n/Title			·
						Reviewer/Title	i			
No. of Staff on site:	_ Physicia	in N	IP C	NM	_ PA	RN LVN	J MA	Clerical	_ Other	
Visit Purpo	se		Site-Spe	cific Cert	ification	(s)	Provider	Туре		Clinic Type
Initial Full Scope Periodic Full Scope Focused Review Other (type)	Ed/TA	-	AAA CHDP CPSP Othe		JCAH NCQA None	Ped	ily Practice liatrics eral Practice l level (type)	Specialist	Hospital Rural Hea	Care Community FQHC alth Other (type) Group Staff/Teaching
	Site So	cores				Ş	Scoring Pro	cedure		Compliance Rate
I. Access/Safety         II. Personnel         III. Office Management         IV. Clinical Services         V. Preventive Services         VI. Infection Control	Points         Poss.         (29)         (23)         (26)         (24)         (12)         (12)         (141)         Total         Pts.         Poss.	Yes Pts. Given Yes Pts. Given	No's	N/A's	CE's	<ol> <li>Add points g</li> <li>Add total po</li> <li>Adjust score subtracting N</li> <li>Divide total p total points.</li> <li>Multiply by 1 rate.</li> <li>Points Tot Given Adju</li> <li>Note: CE's colu</li> </ol>	iven in each sec ints given for al for "N/A" criter I/A points from points given by LOO to get the c LOO to get the c =	ction.	ence to Nort Review	ampted Pass: 90% or above hout deficiencies in Critical ments, Pharmaceutical Services infection Control) mditional Pass: 80-89%, or 6 and above with deficiencies in ical Elements, Pharmaceutical vices or Infection Control t Pass: Below 80% P Required her follow-up tw Due:

# OB Site Review Guidelines 2012

Attachment B

California Department of Health Care Services Medi-Cal Managed Care Division

**<u>Purpose</u>**: Site Review Guidelines provide the standards, directions, instructions, rules, regulations, perimeters, or indicators for the site review survey. These Guidelines shall be used as a gauge or touchstone for measuring, evaluating, assessing, and making decisions.

**Scoring:** Site survey includes on-site inspection and interviews with site personnel. Reviewers are expected to use reasonable evidence available during the review process to determine if practices and systems on site meet survey criteria. Compliance levels include:

1) Exempted Pass: 90% or above *without deficiencies* in Critical Elements, Pharmaceutical or Infection Control

2) Conditional Pass: 80-89%, or 90% and above with deficiencies in either Critical Elements, Pharmaceutical or Infection Control 3) Not Pass: below 80%

A corrective action plan (CAP) is required for a total score less than 90%, OR for a total score of 90% or above if there are deficiencies in Critical Elements, Pharmaceutical Services or Infection Control. Compliance rates are based on 141 total possible points, or on the total "adjusted" for Not Applicable (N/A) items. "N/A" applies to any scored item that does not apply to a specific site as determined by the reviewer. Reviewers are expected to determine how to ascertain information needed to complete the survey. Survey criteria to be reviewed only by a R.N. or physician is labeled **\diamond ORN/MD Review only** 

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

- 1) Add the points given in each section.
- 2) Add points given for all six (6) sections to determine total points given for the site.
- 3) Subtract all "N/A" items from 141 total possible points to determine the "adjusted" total possible points. If there are no "N/A" items, calculation of site score will be based on 141 points.
- 4) Divide the total points given by 141 or by the "adjusted" total. Multiply by 100 to calculate percentage rate.

Scoring Example:

<b><u>Step 1</u></b> : Add the points given in each section.	Step 2: Add points given for all six (6) sections.					
	Example: 29 (Access/safety) (-1 NA)					
	23 (Personnel) 26 (Office Management)					
	24 (Clinical Services) 12 (Preventive Services)					
	<u>27</u> (Infection Control)					
	141 (POINTS)					
<b><u>Step 3</u></b> : Subtract "N/A" points from 141 total points possible.	<b>Step 4</b> : Divide total points given by 141- the "adjusted" points, then					
141(Total points possible)	multiply by 100 to calculate percentage rate.					
<u>– 1 NA</u> 140 ("Adjusted" total points possible)	Points given <u>141</u>					
140 (Adjusted total points possible)	141 or "adjusted" total or $141 = 0.10 \text{ X} 100 = 100\%$					

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Criteria	I. Access/Safety Reviewer Guidelines
A. Site is accessible and useable by individuals with physical disabilities.	ADA Regulations: Site must meet city, county and state building structure and access ordinances for persons with physical disabilities. A site/facility includes the building structure, walkways, parking lots, and equipment. All facilities designed, constructed; or altered by, on behalf of, or for the use of a public entity must be readily accessible and usable by individuals with disabilities, if the construction or alteration was begun after January 26, 1992 (28 CFR 35.151). Any alteration to a place of public accommodation or a commercial facility, after January 26, 1992, usut be made to ensure that, to the maximum extent feasible, the altered portions of the facilities are readily accessible to and useable by individuals with disabilities, including individuals who use wheelchairs (28 CFR 36.402). Parking: Parking space reserved for the disabled is identified by a permanently affixed reflectorized sign posted in a conspicuous place. If provider has no control over availability of disabled parking lot or nearby street spaces, provider must have a plan in place for making program services available to persons with physical disabilities. <b>Ramps</b> : A clear and level landing is at the top and bottom of all ramps and on each side of an exit door. Any path of travel is considered a ramp if its slope is greater than a 1-foot rise in 20 feet of horizontal run. <b>Exit doors</b> : The width of exit doorways (at least 32-in. or reasonable accommodation) allows for passage clearance of a wheelchair. Exit doors include all doors required for access, circulation and use of the building and facilities, such as primary entrances and passageway doors. Furniture and other items do not obstruct exit doorways or interfere with door swing pathway. <b>Elevators</b> : If there is no passenger leevator, a freight elevator may be used to achieve program accessibility if it is upgraded for general passenger use and if passageways leading to and from the elevator are well-lit, neat and clean. <b>Clear Floor Space</b> : Clear space in waiting/exam areas
	<u>Note</u> : A public entity may not deny the benefits of its program, activities, and services to individuals with disabilities because its facilities are inaccessible (28 CFR 35.149-35.150). Every feature need not be accessible, if a reasonable portion of the facilities and accommodations provided is accessible (Title 24, Section 2-419, California Administrative Code, the State Building Code). Reasonable Portion and/or Reasonable Alternatives are acceptable to achieve program accessibility. Reasonable Portion applies to multi-storied structures and provides exceptions to the regulations requiring accessibility to all portions of a facility/site. Reasonable Alternatives are methods other than site structural changes to achieve program accessibility, such as acquisition or redesign of equipment, assignment of assistants/aides to beneficiaries, provision of services at alternate accessible sites, and/or other site specific alternatives to provide services (ADA, Title II, 5.2000). Points shall not be deducted if Reasonable Portion or Reasonable Alternative is made available on site. Specific measurements are provided strictly for "reference only" for the reviewer. Site reviewers are NOT expected to measure parking areas, pedestrian path of travel walkways and/or building

# I. Access/Safety (continued on next page)

1)		
1)	1	
2)	1	
3)	1	
4)	1	
5)	1	
6)	1	
7)	1	
- -	4) 5) 6) 7)	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$

Total pts possible: 7

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Criteria	I. Access/Safety Reviewer Guidelines
B. Site environment is maintained in a clean and sanitary condition.	The physical appearance of floors/carpets, walls, furniture, patient areas and restrooms are clean and well maintained. Appropriate sanitary supplies, such as toilet tissue, hand washing soap, cloth/paper towels or antiseptic towelettes are made available for restroom use. Environmental safety includes the "housekeeping" or hygienic condition of the site. Clean means unsoiled, neat, tidy, and uncluttered. Well maintained means being in good repair or condition.
C. Site environment is safe for all patients, visitors and personnel.	Ordinances: Sites must meet city, county and state fire safety and prevention ordinances. Reviewers should be aware of applicable city and county ordinances in the areas in which they conduct reviews.         Non-medical emergency procedures: Non-medical emergencies include incidents of fire, natural disaster (e.g. earthquakes), workplace violence, etc. Specific information on site, and <i>how to use</i> information. Evidence of training must be verifiable, and may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc.         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.         Illumination:       Lighting is adequate in patient flow working and walking areas such as corridors, walkways, waiting and exam rooms, and restrooms to allow for a safe path of travel.         Access Aisle:       Accessible pedestrian paths of travel (ramps, corridors, walkways, lobbies, elevators, etc.) between elements (seats, tables, displays, equipment, parking spaces, etc.) provide a clear circulation path. Means of egress (escape routes) are maintained free of obstructions or impediments to full instant use of the ravel for pedestrian and/or wheelchair uses at all times when the site is occupied. Cords (including taped cords) or other items are not placed on or across walkway areas.         Exitize: Exit doorways are unobstructed path of travel for pedestrians and/or wheelchair uses, or frayed or cracked areas. Cords are not affixed to structures, placed in or across walkways, extended through walls, floors, and ce

# I. Access/Safety (continued on next page)

Site Access/Safety Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>B.</b> Site environment is maintained in a clean and sanitary condition. 8 CCR §5193; 28 CCR §1300.80					
1) All patient areas including floor/carpet, walls, and furniture are neat, clean and well maintained.	1)	1)	1)	1	
2) Restrooms are clean and contain appropriate sanitary supplies.	2)	2)	2)	1	
<b>C. Site environment is safe for all patients, visitors and personnel.</b> 8 CCR §3220; 22 CCR §53230; 24 CCR, §2, §3, §9; 28 CCR §1300.80; 29 CFR §1910.301, §1926.34					
There is evidence that staff has received safety training and/or has safety information available in the following: 1) Fire safety and prevention	1)	1)	1)	1	
2) Emergency non-medical procedures (e.g. site evacuation, workplace violence)	2)	2)	2)	1	
The following fire and safety precautions are evidenced on site:		/	/	1	
3) Lighting is adequate in all areas to ensure safety.	3)	3)	3)	1	
4) Exit doors and aisles are unobstructed and egress (escape) accessible.	4)	4)	4)	2	
5) Exit doors are clearly marked with "Exit" signs.	5)	5)	5)	1	
6) Clearly diagramed "Evacuation Routes" for emergencies are posted in a visible location.	6)	6)	6)	1	
7) Electrical cords and outlets are in good working condition.	7)	7)	7)	1	
8) At least one type of fire fighting/protection equipment is accessible at all times.	8)	8)	8)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and " $N/\Lambda$ " scores	Total nts n				

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Total pts possible: 11

Criteria	I. Access/Safety Reviewer Guidelines
Criteria D. Emergency health care services are available and accessible 24 hours a day, 7 days a week. 💮 🗁	Site Specific Emergency procedures:       Staff is able to describe site-specific actions or procedures for handling medical emergencies until the individual is stable or under care of local emergency medical services (EMS). 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 MD or NPMP is not onsite, 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 medical conditions that occur on site until the emergent situation is stabilized and/or treatment is initiated by the local 911 Emergency Medical Service (EMS) system. Minimum emergency equipment is available on site to: <ul> <li>establish and maintain a patent/open airway, and</li> <li>manage anaphylactic reaction.</li> <li>Emergency equipment and medication, appropriate to patient population, are available in an accessible location. An accessible location is one that is reachable by personnel standing on the floor, or other permanent working area, without locating/retrieving step stool, ladder or other assistive devices. For emergency "Crash" cart/kit, contents are appropriately sealed and are within the expiration dates posted on label/seal. Site personnel are appropriately trained and can demonstrate knowledge and correct use of all medical equipment they are expected to operate within their scope of work. Documented evidence that emergency equipment is checked at least monthly may include a log, checklist or other appropriate method(s).</li> <li>Emergency phone number list: Postel list includes local emergency</li></ul>
	personnel at the site must demonstrate that they can turn on the oxygen tank.
	medication dosages (e.g. adult, pediatric, infant, etc.). Package inserts are not acceptable as dosage charts. <b>Note:</b> An "emergency medical condition" is a medical condition that manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: 1) placing the health of the individual (or unborn child of a pregnant woman) in serious jeopardy, 2) serious impairment to bodily functions, and 3) serious dysfunction of any bodily organ or part. "Emergency services" means those services required for alleviation of severe pain or immediate diagnosis and treatment of unforeseen medical conditions, which, if not immediately diagnosed and treated, would lead to disability or death.

# I. Access/Safety (continued on next page)

😰 🗁 RN/MD Review only	Yes	No	N/A	Wt.	Site
Site Access/Safety Survey Criteria	res	INO	IN/A	vv ۱.	Site
<b>D.</b> Emergency health care services are available and accessible 24 hours a day, 7 days a week. 22 CCR §51056, §53216; 28 CCR §1300.67 fi} •					
1) Personnel are trained in procedures/action plan to be carried out in case of medical emergency on site.	1)	1)	1)	1	
2) Emergency equipment is stored together in easily accessible location.	2)	2)	2)	1	
3) Emergency phone number contacts are posted.	3)	3)	3)	1	
Emergency medical equipment appropriate to practice/patient population is available on site: 4) <u>Airway management: oxygen delivery system, oral airways, nasal cannula or mask, Ambu bag</u> .	4)	4)	4)	2	
5) Anaphylactic reaction management: Epinephrine 1:1000 (injectable), and Benadryl 25 mg. (oral) or Benadryl 50 mg./ml. (injectable), appropriate sizes of ESIP needles/syringes and alcohol wipes.	5)	5)	5)	1	
6) Medication dosage chart (or other method for determining dosage) is kept with emergency medications.	6)	6)	6)	1	
There is a process in place on site to: 7) Document checking of emergency equipment/supplies for expiration and operating status at least monthly.	7)	7)	7)	1	
8) Replace/re-stock emergency equipment immediately after use. <b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores.	8)	8)	8)	1	

Total pts possible: 9

Criteria	I. Access/Safety Reviewer Guidelines
E. Medical and lab equipment	Medical and laboratory equipment: All equipment used to measure or assess patient health status/condition is clean.
used for patient care is properly maintained. 👧 🗁	<b>Documentation</b> : There is documented evidence that standard operating procedures have been followed for routine inspection/ maintenance, calibration, repair of failure or malfunction, and testing and cleaning of all specialized equipment. Appropriate written records include calibration or other written logs, work orders, service receipts, dated inspection sticker, etc.
	All equipment used to measure or assess patient health status/condition is functioning properly. All specialized equipment (e.g., ultrasonography equipment, electrocardiogram (EKG) machine, defibrillator, audiometer, hemoglobin meter, Glucometer, scales, etc.) are adequately maintained according to the specified manufacturer's guidelines for the equipment, or is serviced annually by a qualified technician. Blood pressure cuffs, monitors, and other related equipment need not be calibrated unless required by the manufacturer. Manufacturer guidelines must be available on site, indicating that it is not necessary to calibrate the equipment.
	Note: The term monitor includes, but not limited to, Glucometer, EKG, BP monitors and HemoCue.

# I. Access/Safety (continued from previous page)

Site Access/Safety Survey Criteria	Yes	No	N/A	Wt.	Site Score
<ul> <li>E Medical and lab equipment used for patient care is properly maintained.</li> <li>CA Health &amp; Safety Code §111255; 28 CCR §1300.80; 21 CFR §800-1299</li> <li>fi} ↔</li> </ul>					
1) Medical equipment is clean.	1)	1)	1)	1	
2) Written documentation demonstrates the appropriate maintenance of all medical equipment according to equipment manufacturer's guidelines.	2)	2)	2)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total pts	possible: 29	9			
TOTAL	S				

Criteria		II. Personnel Rev	viewer Guidelines			
	Medical Professional	License/C	Certification	Issuing Agency		
A. Professional health care personnel have current	Certified Nurse Midwife (CNM)	RN License & Nurse-Mid DEA Registration, <i>if app</i>		CA Board of Registered Nursing Drug Enforcement Administration (DEA)		
California licenses and	Certified Radiological Technologist (CRT)	CRT Certificate.		CDPH, Radiologic Health Branch		
certifications.	Doctor of Osteopathy (DO)	Physician's & Surgeon's DEA Registration	Certificate.	Osteopathic 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 Certifi Number. DEA Registration	6	CA Board of Registered Nursing DEA		
	Pharmacist (Pharm. D)	Pharmacist License		CA State Board of Pharmacy		
	Physician/Surgeon (MD)	Physician's & Surgeon's DEA Registration	Certificate.	Medical Board of CA DEA		
	Physicians' Assistant (PA)	PA License. DEA Registration, <i>if appropriate</i>		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)	CA Board of Registered Nursing				
	lists of currently certified or credentialed per         Note:         Effective June 27, 2010, per CCR, Title 1         Business and Professions Code section 138, MI         Osteopaths) shall provide notification to each pa         site is licensed and regulated by the Board, and	6, 1355.4, mandated by Ds (does not apply to atient that states the MD(s) on	able when requested by reviewers. Note: Effective August 11, 2011, per CCR, Title 16, 1399.547, mandated by Business and Professions Code section 138, PAs shall provide notification t each patient that states the PA(s) is licensed and regulated by the Physician Assistant Committee, and includes the following:			
	NOTICE Medical doctors are licensed by the Medical Board of (800) 633-2322 www.mbc.ca.gov	California	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: 1) prominently posted sign in an area visible to patients in at least 48-pt Arial font, 2) 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 Committee), or 3) 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 a at least 14-pt font.					
B. Health care personnel are properly identified.	personnel in a practice or an office, whose I consumer awareness, it shall be unlawful fo individual who is a registered nurse, or a lic that are the subject of licensure or regulatio	icense is prominently display or any person to use the title ensed vocational nurse. <u>Not</u> n under the CA B&P Code ( in a setting that is not license	yed, to opt not to wear a "nurse" in reference to h <u>e:</u> "Health care practition Section 680-681). If a he ed by the state, the empl	18-point type. It is acceptable for health care nametag. In the interest of public safety and imself or herself, in any capacity, except for an ner" means any person who engages in acts ealth care practitioner or licensed clinical social loying entity or agency shall have the discretion cerns.		

### II. Personnel (continued on next page)

Site Personnel Survey Criteria	Yes	No	N/A	Wt.	Site Score
<ul> <li>A. Professional health care personnel have current California licenses and certifications. CA Business &amp; Professional (B&amp;P) Code §2050, §2085, §2725, §2746, §2834, §3500, §4110; CCR, Title 16, §1355.4, §1399.547</li> <li>1) All required Professional Licenses and Certifications, issued from the appropriate licensing/certification agency, are current. Notification is provided to each member that the MD(s) is licensed and regulated by the Medical Board, and that the Physician Assistant(s) is licensed and regulated by the Physician Assistant Committee.</li> </ul>	1)	1)	1)	1	
<b>B. Health care personnel are properly identified.</b> CA B&P Code §680, AB 1439					
1) Health care personnel wear identification badges/tags printed with name and title.	1)	1)	1)	1	

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Total points possible: 2

Criteria	II. Personnel Reviewer Guidelines
and trained for assigned responsibilities.	<ul> <li>Indical equipment: Provider and/or staff are able to demonstrate appropriate operation of medical equipment used in their cope of work. Not all staff is required to be proficient in use of all equipment.</li> <li>Indicensed personnel: Medical assistants (MA) are unlicensed health personnel, at least 18 years of age, who perform basic fininistrative, clerical, and non-invasive routine technical supportive services under the supervision of a licensed physician, rigeon or podiatrist in a medical office or clinic setting. Supervision means the licensed physician must be physically present in the transmit of the performance of authorized procedures by the MA. 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. The pervising physician is responsible for determining the training content and ascertaining proficiency of the MA. Training commentation of non an accredited training program/school, or</li> <li>Diploma or certification from an accredited training program/school, or</li> <li>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.</li> <li>Comprehensive Perinatal Services Program (CPSP) sites must have documentation of training and supervision in all medication from instration methods performed within their scope of work. Medication administration by a MA means the direct application of re-measured medication orally, sublingually, topically, vaginally or rectally; or by providing a single dose to a patient for nunediate self-administration by subcutaneous or intramuscular injection, or to perform intradermal skin tests or venipunctures for thdrawing blood, an MA must have completed at least the minimum number of training, hourse stablished in CCR, Title 16, ecciton 366.1. MAs cannot administer anesthetics, i</li></ul>

### II. Personnel (continued on next page)

Site Personnel Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>C. Site personnel are qualified and trained for assigned responsibilities.</b> CA B&P Code §2069; 16 CCR §1366; 22 CCR §75034, §75035 fi} ↔					
1) Only qualified/trained personnel retrieve, prepare or administer medications.		1)	1)	2	
2) Only qualified/trained personnel operate medical equipment.		2)	2)	1	
<ul> <li>3) Documentation of education/training for non-licensed medical personnel is maintained on site.</li> <li>4) Documentation of education/training for CPSP Certified staff is maintained on site.</li> </ul>		3) 4)	3) 4)	1 1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores.	Total points	possible: 5	1	1	<u> </u>

Criteria	II. Personnel Reviewer Guidelines
D. Scope of practice for non- physician medical practitioners (NPMP) is clearly defined.	Reviewers are expected to verify that NP and/or CNM standardized procedures, and PA Delegation of Services Agreement and Supervision Physician's Responsibility documentation are present on site. Reviewers are <i>not</i> expected to make in-depth evaluation of "appropriateness" of the NPMP's scope of practice. Documents may be utilized to determine and/or clarify practice procedures and supervisory processes on site.
	<u>Certified Nurse Midwives</u> (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.
	<u>Nurse Practitioners</u> (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.
	<b>Physician Assistants</b> (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.
	<ul> <li>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:</li> <li>a) Transport and back-up procedures for when the supervising physician is not on the premises.</li> </ul>
	<ul> <li>b) One or more methods for performing medical record review by the supervising physician:</li> <li>c) Responsibility for physician review and countersigning of medical records</li> <li>d) Responsibility of the PA to enter the name of approved supervising physician responsible for the patient on the medical record.</li> </ul>
	<b>Drug Enforcement Agency</b> (DEA): Each NP, CNM, and PA that prescribes controlled substances is required to have a valid DEA Registration Number.
	<u>Note</u> : Standardized procedures legally define the expanded scope of nursing practice that overlaps the practice of medicine. CNMs and NPs operate under written Standardized Procedures that are collaboratively developed and approved by the supervising physician, the NP and administration within the organized health care facility/system in which standardized procedures will be used. 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. Standardized Procedures shall undergo periodic review, with signed, dated revisions completed at each change in scope of work.

### II. Personnel (continued on next page)

Site Personnel Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>D. Scope of practice for non-physician medical practitioners (NPMP) is clearly defined.</b> 16 CCR §1379, §1399.540, §1399.545, §1474, CA B&P Code §2725.1 fi} •					
1) Standardized Procedures provided for Nurse Practitioners (NP) and/or Certified Nurse Midwives (CNM).	1)	1)	1)	1	
2) A Delegation of Services Agreement defines the scope of services provided by Physician Assistants (PA) and Supervisory Guidelines define the method of supervision by the Supervising Physician.	2)	2)	2)	1	
3) Standardized Procedures, Delegation of Services Agreements and Supervisory Guidelines are revised, updated <u>and</u> signed by the supervising physician and NPMP when changes in scope of services occur.	3)	3)	3)	1	
4) Each NPMP that prescribes controlled substances has a valid DEA Registration Number.	4)	4)	4)	1	

Criteria	II. Personnel Reviewer Guidelines
E. Non-physician medical practitioners (NPMP) are supervised according to established standards.	<ul> <li><u>Non-physician medical practitioners</u>: The Supervising Physician holds ultimate responsibility for the practice of each supervised non-physician medical practitioner. 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: 4 nurse practitioners, 3 nurse midwives, 4 physician's assistants or 4 of the above individuals in any combination which does not exceed the limit stated. This ratio is based on each physician, not the number of offices. A primary care physician, an organized outpatient clinic or a hospital outpatient department cannot utilize more non-physician medical practitioners than can be supervised within these stated limits.</li> <li>Ref: Assembly Bill 3 Bass, Chapter 376, October 2007, effective January 1, 2008, allows 4 PAs to 1 MD; Business &amp; Professions Code 3516(b); W &amp; I Code 14132.966. Physician Assistant Committee is at: <a href="http://www.pac.ca.gov/orthePAC">http://www.pac.ca.gov/orthePAC</a> office at 916-561-8780.</li> </ul>
	<b>Supervising physician</b> : "Supervising physician" means a physician and/or surgeon licensed by the Medical Board or by the Osteopathic Medical Board of California who supervises one or more physician assistants, possesses a current valid license to practice medicine, and is not currently on disciplinary probation for improper use of a physician assistant. "Supervision" means that a licensed physician and surgeon oversee the activities of, and accept responsibility for, the medical services rendered by a physician assistant. Physicians must comply with all current and/or revised requirements established by the Medical Board of CA for supervising physician assistants.

### II. Personnel (continued on next page)

Site Personnel Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>E. Non-physician medical practitioners (NPMP) are supervised according to established standards.</b> B&P Code 3516(b); W&I Code 14132.966 fi}					
<ul> <li>The designated supervising physician(s) on site:</li> <li>1) ratio to number of NPMPs does not exceed established ratios in any combination.</li> <li>a) 1:4 Nurse Practitioners</li> <li>b) 1:3 Certified Nurse Midwives</li> <li>c) 1:4 Physicians Assistants</li> </ul>	1)	1)	1)	1	
2) The designated supervising or back-up physician is available in person or by electronic communication at all times when a NPMP is caring for patients.	2)	2)	2)	1	
Comments: Write comments for all "No" (0 points) and "N/A" scores.	Total points p	possible: 2		I	1

Criteria	II. Personnel Reviewer Guidelines
F. Site personnel receive safety training/information. ∰ ☐	Bloodborne Pathogens:       Site personnel treat all blood and other potentially infectious materials (OPIM) as if these are infectious. Site personnel who are reasonably anticipated to have eye, skin, mucous membranes and potential exposure to blood and/or other potentially infectious materials (OPIM) receive training as required by the Bloodborne Pathogens Standard, Title 8, CCR, Section 5193. Training occurs prior to initial exposure to potentially infectious and/or biohazardous materials. Review and re-training sessions occur at least annually. Training content is appropriate (language, educational level, etc.) to personnel on site. Training minimally includes the following: <ul> <li>universal/standard precautions</li> <li>use of personal protective equipment</li> <li>accessible copy of Bloodborne Pathogens</li> <li>epidemiology/symptoms of HBV and HIV</li> <li>recognition of activities with exposure element</li> <li>handling and labeling of biohazarous waste(s)</li> <li>Hepatitis B vaccination protocol and requirements</li> <li>explanation of emergency procedures</li> <li>post exposure reporting/evaluation/follow-up procedures</li> <li>decontamination of equipment/work areas</li> </ul>
	site's written Bloodborne pathogen exposure plan
	<ul> <li>opportunity for discussion/questions</li> <li>Personnel must know <i>where to locate</i> information/resources on site about infection control, the Bloodborne Pathogens Exposure Plan, and <i>how to use</i> the information. Evidence of training must be verifiable. Evidence of training may include informal inservices, new staff orientation, external training courses, educational curriculum and participation lists, etc. Training documentation must contain the employee's name, job titles, training date(s), type of training, contents of training session, and names/qualifications of trainers. Records must be kept for three (3) years.</li> </ul>
	Abuse Reporting:Site personnel have specific knowledge of local reporting requirements, agencies, and procedures, and know where to locate information on site and how to use information.Note:Health practitioners (e.g., physicians, surgeons, licensed nurses, licensed social workers, paramedics) in a health facility, (e.g., clinic, physician's office, public health clinic) are legally mandated reporters of known or reasonably suspected cases of child abuse, elder abuse and domestic violence. Legally mandated reporters must make telephone and written reports according to timeliness standards established 

### II. Personnel (continued on next page)

Site Personnel Survey Criteria	Yes	No	N/A	Wt.	Site Score
<ul> <li>F. Site personnel receive safety training/information.</li> <li>8 CCR §5193; CA H&amp;S Code §117600; CA Penal Code §11164, §11168; 29 CFR §1910.1030 fi} </li> </ul>					
There is evidence that site staff has received training and/or information on the following:					
1) Infection control/universal precautions (annually)		1)	1)	1	
2) Blood Borne Pathogens Exposure Prevention (annually)		2)	2)	1	
3) Biohazarous Waste handling (annually)		3)	3)	1	
4) Child/Elder/Domestic Violence Abuse		4)	4)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores.	Total points j	possible: 4			

Criteria	II. Personnel Reviewer Guidelines
G. Site personnel receive training and/or information on member rights.	Site personnel have received information and/or training about member rights. Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. If there is no verifiable evidence of staff training, staff is able to locate written member rights information on site and explain how to use information.

### II. Personnel (continued from previous page)

Site Personnel Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>G. Site personnel receive training and/or information on member rights.</b> 22 CCR §51009, §51014.1, §51305.1, §53452, §53858; 28 CCR §1300.68 fi} <b>O</b>					
There is evidence that site staff has received training and/or information on the following:					
1) Patient Confidentiality	1)	1)	1)	1	
2) Informed consent, including Human Sterilization	2)	2)	2)	1	
3) Prior Authorization requests	3)	3)	3)	1	
4) Grievance/Complaint Procedure	4)	4)	4)	1	
5) Sensitive Services/Minors' Rights	5)	5)	5)	1	
6) Health Plan referral process/procedures/resources	6)	6)	6)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 6					
Totals					

### 👧 🗁 RN/MD Review only (#B)

Criteria	III. Office Management Reviewer Guidelines
<ul> <li>A. Physician coverage is available 24 hours a day,</li> <li>7 days a week.</li> </ul>	Current clinic office hours are posted within the office or readily available upon request. Current site-specific resource information is available to site personnel about physician office hour schedule(s), local and/or Plan-specific systems for after-hours urgent care, emergent physician coverage available 24 hours a day, 7 days per week, and system for providing follow-up care. When a physician is not on site during regular office hours, personnel are able to contact the physician (or covering physician) at all times by telephone, cell phone, pager, etc.
	<u>Note</u> : One objective of effective clinic office management is to support the provision of appropriate, coordinated health care services. The review of clinic office management is to evaluate if effective systems are in place and whether site personnel appropriately follow established site-specific procedures.
B. There is sufficient health care personnel to provide timely, appropriate health care services. 💮 🗁	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. The California Board of Vocational Nursing and Psychiatric Technician Examiners have determined that the Licensed Vocational Nurse Practice Act <i>does not</i> permit the LVN to perform triage independently (MCPB Letter 92-15). The LVN may perform that part of the triage process that includes observation and data collection relative to basic physical assessment. The LVN <i>may not</i> perform that part of the triage process that includes independent evaluation, interpretation of data, and determination of treatment priorities and levels of care. Unlicensed personnel, such as medical assistants, may provide patient information or instructions only as authorized by the physician (Title 16, §1366 (b)).
	Note: Telephone triage is the system for managing telephone callers during and after office hours.

# III. Office Management (continued on next page)

Yes	No	N/A	Wt.	Site Score
1)	1)	1)	1	
2)	2)	2)	1	
3)	3)	3)	1	
4)	4)	4)	1	
5)	5)	5)	1	
1)	1)	1)	1	
2)	2)	2)	1	
3)	3)	3)	1	
	1)         2)         3)         4)         5)         1)         2)	1)       1)         2)       2)         3)       3)         4)       4)         5)       5)         1)       1)         2)       2)	1)       1)       1)         2)       2)       2)         3)       3)       3)         4)       4)       4)         5)       5)       5)         1)       1)       1)         2)       2)       2)	1)       1)       1)       1         2)       2)       1         3)       3)       3)       1         4)       4)       4)       1         5)       5)       5)       1         1)       1)       1       1         2)       2)       2)       1         1       1       1       1         2)       2)       2)       1       1

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Total points possible: 8

### 👧 🗁 RN/MD Review only (#C)

Criteria	III. Office Management Reviewer Guidelines
C. Health care services are readily available.	The process established on site provides timely access to appointments for routine care, urgent care, prenatal care, pediatric periodic health assessments/immunizations, adult initial health assessments, specialty care and emergency care. An organized system must be clearly evident (in use) for scheduling appointments appropriately, notifying and reminding members of scheduled appointments, and following up of missed or canceled appointments. Systems, practices and procedures used for making services readily available to patients will vary from site to site.
	The comprehensive risk assessments shall be administered at the initial prenatal visit, once each trimester thereafter and at the postpartum visit. Risks identified shall be followed up by appropriate interventions, which must be documented with appropriate follow-up in the medical record The results of the assessment and individual care plan shall be maintained in the medical record and include medical/obstetrical and nutrition, health education, and psychosocial risk assessment components.
	Missed and/or canceled appointments, and contact attempts must be documented in the patient's medical record.
D. There is 24-hour access to interpreter services for non- or limited-English proficient (LEP) members.	All sites must provide 24-hour interpreter services for all members either through telephone language services or interpreters on site. Site personnel used as interpreters have been assessed for their medical interpretation performance skills/capabilities. A family member or friend may be used as an interpreter if requested by the LEP individual after being informed of their right to use free interpreter services.
	<u>Note</u> : Assessment of interpreter skills may include written or oral assessment of bilingual skills, documentation of the number of years of employment as an interpreter or translator, documentation of successful completion of a specific type of interpreter training programs (medical, legal, court, semi-technical, etc.), and/or other reasonable alternative documentation of interpreter capability. A request for or refusal of language/ interpreter services must be documented in the member's medical record.

### III. Office Management (continued on next page)

#### 💮 🗁 RN/MD Review only (#C)

Office Management Survey Criteria		No	N/A	Wt.	Site Score
C. Health care services are readily available.					
22 CCR §56000(2) fi} •					
1) Appointments are scheduled according to patients' stated clinical needs within the timeliness standards established for Plan members.	1)	1)	1)	1	
2) Patients are notified of scheduled routine and/or preventive screening appointments.	2)	2)	2)	1	
3) There is a process in place verifying follow-up on missed and canceled appointments.	3)	3)	3)	1	
4) Partnership Health Plan members have access to CPSP services.	4)	4)	4)	1	
D. There is 24-hour access to interpreter services for non- or limited-English proficient (LEP)					
<b>members.</b> 22 CCR §53851; 28 CCR 1300.67.04					
1) Interpreter services are made available in identified threshold languages specified for location of site.	1)	1)	1)	1	
2) Persons providing language interpreter services on site are trained in medical interpretation.	2)	2)	2)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 6					

IF CPSP SERVICES (PSYCHOSOCIAL AND NUTRITION) ARE NOT PROVIDED BY THIS SITE, WITH WHOM ARE THEY CONTRACTED TO PROVIDE THESE SERVICES?

### 👧 🗁 RN/MD Review only (#E)

Criteria	III. Office Management Reviewer Guidelines
E. Procedures for timely referral/ consultative services are established on site. 👧 🗁	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.
F. Member grievance/ complaint processes are established on site.	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.
	<u>Note</u> : A "grievance" is defined as any written or oral expression of dissatisfaction and shall include any complaint, dispute, and request for reconsideration or appeal made by an enrollee or their representative to a Plan or entity with delegated authority to resolve grievances on behalf of the Plan.

### II. Office Management (continued on next page)

👧 🗁 RN/MD Review only (#E)

Office Management Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>E. Procedures for timely referral/consultative services are established on site.</b> 22 CCR §53851; 28 CCR §1300.67 and §1300.80 fi}					
Office practice procedures allow timely provision and tracking of: 1) Processing internal and external referrals, consultant reports and diagnostic test results	1)	1)	1)	1	
2) Physician review and follow-up of referral/consultation reports and diagnostic test results.	2)	2)	2)	2	
<b>F. Member Grievance/Complaint processes are established on site.</b> 22 CCR §53858, §56260					
1) Phone number(s) for filing grievances/complaints are located on site.	1)	1)	1)	1	
2) Complaint forms and a copy of the grievance procedure(s) are available on site.	2)	2)	2)	1	

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Total points possible: 5

### 👧 🗁 RN/MD Review only (#H)

Criteria	III. Office Management Reviewer Guidelines
G. Medical records are available for the practitioner at each scheduled patient encounter.	The process/system established on site provides for the availability of medical records (paper and electronic), including outpatient, inpatient, referral services, and significant telephone consultations for patient encounters. Medical records are filed that allows for ease of accessibility within the facility, or in an approved health record storage facility off the facility premises (22 CCR, § 75055).
H. Confidentiality of personal medical information is protected according to State and federal guidelines.	<ul> <li>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.</li> <li>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.</li> <li>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.</li> <li>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, 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.</li> <li>Record retention: Hospitals, acute psychiatric hospitals, skilled nursing facilities, <i>primary care clinics</i>, psychology and psychiatric clinics must maintain medical records and exposed x-rays for a minimum of 7 years following patient discharge, except for minors (Title 22, CCR, an</li></ul>

# III. Office Management (continued from previous page)

Yes	No	N/A	Wt.	Site Score
1)	1)	1)	1	
2)	2)	2)	1	
1)	1)	1)	1	
2)	2)	2)	1	
3)	3)	3)	1	
4)	4)	4)	1	
5)	5)	5)	1	
	2) 1) 2) 3) 4)	2)       2)         1)       1)         2)       2)         3)       3)         4)       4)	2)       2)       2)         1)       1)       1)         2)       2)       2)         3)       3)       3)         4)       4)       4)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

Totals

Criteria	IV. Clinical Services - Pharmaceutical Reviewer Guidelines
A. Drugs and medication supplies are maintained secured to prevent unauthorized access.	Deficiencies:       All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, etc.) must be addressed in a corrective action plan.         Controlled substances:       Written records are maintained of controlled substances inventory list(s) that includes: provider's DEA number, name of medication, original quantity of drug, dose, date, name of patient receiving drug, name of authorized person dispensing drug, and number of remaining doses. Controlled substances are stored separately from other drugs in a securely locked, substantially constructed cabinet (Control Substances Act, CFR 1301.75). Control substances include all Schedule I, II, III, IV, and V substances listed in the CA Health and Safety Code, Sections 11053-11058, and do not need to be double locked. Personnel with authorized access to controlled substances include physicians, dentists, podiatrists, physician's assistants, licensed nurses and pharmacists.         Security:       All drugs for dispensing are stored in an area that is secured at all times (CA B&P Code, §4172). Keys to locked storage area are available only to staff authorized by the physician to have access (16 CCR, Chapter 2, Division 13, Section 1356.3). 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.
	<u>Note</u> : During business hours, the drawer, cabinet or room containing drugs, medication supplies or hazardous substances may remain unlocked only if there is no access to area by unauthorized persons. Whenever drugs, medication supplies or hazardous substances are unlocked, authorized clinic personnel must remain in the immediate area at all times. At all other times, drugs, medication supplies and hazardous substances must be securely locked. Controlled substances are locked at all times.

# IV. Clinical Services - Pharmaceutical (continued on next page)

Pharmaceutical Services Survey Criteria		No	N/A	Wt.	Site Score
<b>A. Drugs and medication supplies are maintained secure to prevent unauthorized access.</b> CA B&P Code §4172; 22 CCR §75037(a-g), §75039; 21 CFR §1301.75, §1301.76, §1302.22; 16 CCR §1356.3					
<ol> <li>Drugs are stored in specifically designated cupboards, cabinets, closets or drawers.</li> <li>Prescription, sample and over-the counter drugs, hypodermic needles/syringes, prescription pads are securely stored in a lockable space (cabinet or room) within the office/clinic.</li> </ol>	1) 2)	1) 2)	1) 2)	1	
<ul><li>3) Controlled drugs are stored in a locked space accessible only to authorized personnel.</li><li>4) A dose-by-dose controlled substance distribution log is maintained.</li></ul>	3) <u> </u>	3) <u> </u>	3)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 4					

Criteria	IV. Clinical Services - Pharmaceutical Reviewer Guidelines
B. Drugs are handled safely and stored appropriately.	<b>Deficiencies:</b> All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, etc.) must be addressed in a corrective action plan.
	<b>Drug preparation</b> : A drug or device is considered "adulterated" if it contains any filthy, putrid, or decomposed substance, or if it has been prepared, packed or held under unsanitary conditions (21 USC, Section 351). 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.
	<b>Storage</b> : 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 (21 CFR, Section 211.142). Room temperature where drugs are stored does not exceed 30°C (86°F) (Title 22, Section 75037 (d)).
	<b>Immunobiologics</b> : Rho GAM is refrigerated immediately upon receipt on site and stored according to specific instructions on the package insert. Vaccines are refrigerated immediately upon receipt on site and stored according to specific instructions on the package insert for each vaccine. Diluent does not need refrigeration if vaccine administered right after Diluent is added. Vaccines are not stored in the doors of the refrigerator or freezer. Refrigerator temperatures are documented at least once a day. Site personnel must be able to verbalize the procedure used to promptly respond to out of range temperatures.
	<u>Refrigerator</u> : Vaccines are kept in a refrigerator <b>maintained at 2-8°C or 35-46°F</b> , and include, but are not limited to, Tdap, Hepatitis A and B, Pneumococcal 23, Influenza (inactivated and FluMist) MCV,HPV. As Zoster, MMR and MMRV are live vaccines and are not given to pregnant women their specific storage requirements are not listed.
	Rho GAM is kept in a refrigerator maintained at 2-8°C or 35-46°F.
	<ul> <li>Hazardous substances labeling: Safety practices are followed in accordance with current/updated CAL-OSHA standards. The manufacturer's label is not removed from a container (bag, bottle, box, can, cylinder, etc.) as long as the hazardous material or residues of the material remain in the container. All portable containers of hazardous chemicals and secondary containers into which hazardous substances are transferred or prepared require labeling. Labels must provide the following information:</li> <li>1) identity of hazardous substance,</li> <li>2) description of hazard warning: can be words, pictures, symbols and</li> <li>3) date of preparation or transfer.</li> </ul>
	<b>Exception</b> : Labeling is not required for portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the individual who performs the transfer.
	<u>Note</u> : The purpose of hazard communication is to convey information about hazardous substances used in the work place. A hazardous substance is any substance that is a physical or health hazard. Examples of a physical hazard include substances that are a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive. Examples of a health hazard include substances where acute or chronic health effects may occur with exposure, such as carcinogens, toxic or highly toxic agents, irritants, corrosives, sensitizers and agents that damage the lungs, skin, eyes, or mucous membranes.

# IV. Clinical Services - Pharmaceutical (continued on next page)

🚱 🗁 RN/MD Review only					
Pharmaceutical Services Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>B. Drugs are handled safely and stored appropriately.</b> 22 CCR §75037(a-g), §75039; 21 CFR §211.137; 21 USC §351 fi} ↔					
1) Drugs are prepared in a clean area, or "designated clean" area if prepared in a multipurpose room.	1)	1)	1)	1	
2) Drugs for external use are stored separately from drugs for internal use.	2)	2)	2)	1	
3) Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.	3)	3)	3)	1	
4) Refrigerator thermometer temperature is 35°-46° Fahrenheit or 2°-8° Centigrade (at time of site visit).	4)	4)	4)	1	
5) Daily temperature readings of medication refrigerator are documented.	5)	5)	5)	1	
6) Drugs are stored separately from test reagents, germicides, disinfectants and other household substances.	6)	6)	6)	1	
7) Hazardous substances are appropriately labeled.	7)	7)	7)	1	
8) Site has method(s) in place for drug and hazardous substance disposal.	8)	8)	8)	1	

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Total points possible: 8

Criteria	IV. Clinical Services - Pharmaceutical Reviewer Guidelines
C. Drugs are dispensed according to State and federal	<b>Deficiencies:</b> All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, etc.) must be addressed in a corrective action plan.
drug distribution laws and regulations.	<b>Expiration date</b> : The manufacturer's expiration date must appear on the labeling of all drugs. All prescription drugs not bearing the expiration date are deemed to have expired. If a drug is to be reconstituted at the time of dispensing, its labeling must contain expiration information for both the reconstituted and unconstituted drug. Expired drugs may not be distributed or dispensed.
	<b>Prescription labeling</b> : Each prescription medication dispensed is in a container that is not cracked, soiled or without secure closures (Title 22, CCR, Section 75037 (a)). Drug container is labeled with the provider's name, patient's name, drug name, dose, frequency, route, quantity dispensed, and manufacturer's name and lot number. California Pharmacy Law <i>does not</i> prohibit furnishing a limited quantity of sample drugs if dispensed to the patient in the package provided by the manufacturer, no charge is made to the patient, and appropriate documentation is made in the patient's medical record (CA Business and Professions Code, Sections 4170, 4171).
	<b>Drug distribution</b> : 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.
	<b>Drug dispensing</b> : Drug dispensing is in compliance with all applicable State and federal laws and regulations. Drugs are dispensed only by a physician; pharmacist or other persons (e.g., NP, CNM, RN, PA) lawfully authorized to dispense medications upon the order of a licensed physician or surgeon. Personnel such as medical assistants, office managers, and receptionists do not dispense drugs. Drugs are not offered for sale, charged or billed to Medi-Cal members (Business and Professions Code, Article 13, Section 4193). A record of all drugs dispensed is entered in the patient's medical record.
	<b>Vaccine Information Statements (VIS)</b> : Since 1994, the National Childhood Vaccine Injury Act, Section 2126 of he Public Health Service Act, mandates that parents/guardians or adult patients be informed before vaccines are administered. Health Care Providers must present and offer a copy of the most recent VIS to parents/guardians or adults prior to any vaccine.* The date of the VIS was given (or presented and offered) <i>and</i> the publication date of the VIS must be documented in the patient's medical record. The most current VIS are available from state and local health departments or can be downloaded from the CDC website at <a href="http://www.cdc.gov/vaccines/pubs/vis/default.htm">http://www.cdc.gov/vaccines/pubs/vis/default.htm</a> or by calling the CDC Immunization Hotline at 800-232-4636. The Vaccines for Children (VFC) also contains the current VIS and provider notifications at <a href="http://www.eziz.org/">http://www.eziz.org/</a> . *VIS published by CDC is to be provided to the parent/guardian/adult prior to administration of that vaccination. (42USC, 300aa-26(D) (2). As of 2009, CDC allows providers to 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 http://www.cdc.gov/vaccines/pubs/vis/vis/tis.htm.
	<b>Pharmacy</b> : If a pharmacy is located on site, a licensed pharmacist monitors drug distribution and policies/procedures for medication dispensing/storage. <u>Note</u> : "Dispensing" of drugs means the furnishing of drugs or devices directly to a patient or upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or upon an order to furnish drugs or transmit a prescription from a certified nurse midwife, nurse practitioner, physician assistant or pharmacist acting within the scope of his or her practice.

# IV. Clinical Services - Pharmaceutical (continued from previous page)

Pharmaceutical Services Survey Criteria		No	N/A	Wt.	Site Score
<b>C. Drugs are dispensed according to State and federal drug distribution laws and regulations.</b> CA B&P Code §4024, §4076, §4170, §4171, §4173, §4174; 22 CCR §75032, §75033, §75036, §75037(a-g), §75038, §75039; 16 CCR §1718.1; 21 CFR §211.137; 42 USC 6A §300AA-26 fi}					
1) There are no expired drugs on site.	1)	1)	1)	1	
2) Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas.	2)	2)	2)	1	
3) All stored and dispensed prescription drugs are appropriately labeled.	3)	3)	3)	1	
4) Only lawfully authorized persons dispense drugs to patients.	4)	4)	4)	2	
5) Current Vaccine Information Sheets (VIS) for distribution to patients are present on site	5)	5)	5)	1	
6) If there is a pharmacy on site, it is licensed by the CA State Board of Pharmacy.	6)	6)	6)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 7	1		1	1	4

Criteria	IV. Clinical Services – Laboratory Reviewer Guidelines
D. Site is compliant with Clinical Laboratory Improvement Amendment (CLIA) regulations.	<ul> <li>CLIA Certificates: 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 submission is present on site or readily available upon request. The CLIA certificate or evidence of renewal should include the current site/clinic address. Note: Per 42 CFR, 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3), laboratories must file a separate application for each laboratory location, with the following <u>exceptions</u>:         <ul> <li>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,</li> <li>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</li> <li>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.</li> <li>Certificate on site includes one of the following:</li></ul></li></ul>
	<ul> <li>Waived tests: If only waived tests are performed, site has a current CLIA Certificate of Waiver. There are no specific CLIA regulations regarding the performance of waived tests. Site personnel are expected to follow the test manufacturer's instructions. Laboratories with certificates of waiver may not be routinely inspected by DHCS Laboratory Field Services Division, but may be inspected as part of complaint investigations and on a random basis to determine whether only waived tests are being performed.</li> <li>Moderate and High complexity tests: Tests not listed as waived are divided into one of two categories, moderate complexity or high complexity, based on the complexity of the testing procedure. CLIA regulations for these categories list specific requirements for laboratory proficiency testing, patient test management, quality control, quality assurance, personnel, and inspections.</li> <li>Personnel training: Prior to testing biological specimens, personnel have been appropriately trained for the type and complexity of the laboratory services performed. Personnel have demonstrated the ability to perform all testing operations reliably and to report results accurately. Site personnel are able to provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results. The required training and certification is established by legislation (CA B&amp;P Codes, §1200-1213) for personnel performing moderate and high complexity tests.</li> </ul>
	<u>Note</u> : Any site that performs tests or examinations on human biological specimens derived from the human body is, by definition, "laboratories" under State and federal law, and includes locations such as nurses' stations within hospitals, clinics, surgical centers, physician offices, and health fairs. The current listing of waived tests may be obtained at <u>www.fda.gov/cdrh/clia/testswaived.html</u> . CLIA re/certification includes an evaluation every two years (or sooner of complaint driven) by CDPH of personnel licenses/training, laboratory site inspection and demonstration of testing proficiency for moderate and high-complexity test sites. Contact CDPH Laboratory Field Services (510) 620-3800 for CLIA certification, laboratory license, or personnel questions.

# **IV. Clinical Services - Laboratory**

Laboratory Services Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>D.</b> Site is compliant with Clinical Laboratory Improvement Amendment (CLIA) regulations. 17 CCR §1050; 22 CCR §51211.2, §51137.2; B&P Code §1220; 42 USC 263a; Public Law 100-578					
1) Laboratory test procedures are performed according to current site-specific CLIA certificate.	1)	1)	1)	1	
2) Testing personnel performing clinical lab procedures have been trained.	2)	2)	2)	1	
3) Lab supplies (e.g. vacutainers, vacutainer tubes, culture swabs, test solutions) are inaccessible to unauthorized persons.	3)	3)	3)	1	
4) Lab test supplies are not expired.	4)	4)	4)	1	
5) Site has a procedure to check expiration date and a method to dispose of expired lab test supplies.	5)	5)	5)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 5	I	1	1	1	1

Criteria	V. Preventive Services Reviewer Guidelines
A. Preventive health care services and health appraisal	<b>Examination table</b> : A protective barrier that is changed between patient contact is used to cover exam table surface. "Good repair" means clean and well maintained in proper working order.
examinations are provided on a periodic basis for the detection of asymptomatic diseases.	Scales: Balance beam or electronic scales are appropriate for clinic use. Balance scales have an adjustment mechanism and zeroing weight to enable routine balancing at zero. Electronic or digital scales have automatic zeroing and lock-in weight features. Spring balance scales (e.g. bathroom scales) are unsatisfactory for clinical use because, over time, the spring counter balance mechanism loses its accuracy.
	Measuring devices: Equipment for measuring height must be available on site.
	<b>Basic equipment</b> : Exam gown sizes are appropriate to population served on site.
	<b>Vision testing</b> : Site has both a literate (e.g. Snellen) and illiterate (e.g. "E" chart, "Kindergarten" chart, Allen Picture Card Test). "Heel" lines are aligned with center of eye chart at a distance of 10 or 20 feet depending on whether the chart is for the 10-foot or 20 foot distance. Eye charts are located in an area with adequate lighting and at height(s) appropriate to use. Disposable eye "occluders" (e.g. Dixie cups or tongue blades with back to back stickers) are acceptable. Non-disposable occluders are cleaned between patients.
	<u>Note</u> : Although patient population varies from site-to-site, screening equipment listed in this section is the standard equipment most often used in performing a physical health screening examination for children and adults.

# V. Preventive Services (continued on next page)

### 👧 🗁 RN/MD Review only

Preventive Services Survey Criteria	Yes	No	N/A	Wt.	Site Score
A. Preventive health care services and health appraisal examinations are provided on a periodic basis for the detection of asymptomatic diseases. 22 CCR §53851, §56210; 28 CCR §1300.67					
Examination equipment, appropriate for primary care services, is available on site: 1) Exam tables and lights are in good repair.					
2) Stethoscope and sphygmomanometer with various size cuffs (e.g. child, adult, obese/thigh).	1)	1)	1)	1	
3) Thermometer with a numeric reading.	2)	2)	2)	1	
4) Scales: standing balance beam	3)	3)	3)	1	
5) Measuring device for stature is present on site	4)	4)	4)	1	
6) Basic exam equipment: percussion hammer, tongue blades, patient gowns.	5) <u> </u>	5) <u> </u>	5)	1	
7) Eye charts (literate and illiterate) and occluder for vision	7)	7)	6) <u> </u>	1	
8) Ophthalmoscope.	8)	8)	8)	1	
9) Otoscope with adult and pediatric ear speculums.	9)	9)	9)	1	

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Total points possible: 9

### 👧 🗁 RN/MD Review only

Criteria	V. Preventive Services Reviewer Guidelines
B. Health education services are available to Plan members.	<b><u>Health Education services</u></b> : 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.
<b>9 - 1</b>	<b>Health Education materials:</b> 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. Materials may include written information, audio and/or videotapes, computerized programs, and visual presentation aids. General topics for health educational materials may include Immunizations, Pregnancy, Injury Prevention, Smoking Cessation, Dental Health, Nutrition, Physical Activity, STD/HIV Prevention, Family Planning, Asthma, Hypertension, and Diabetes.
	<b>Plan-specific Referral information:</b> 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 <i>each</i> 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.
	<b>Note:</b> 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.

# V. Preventive Services (continued from previous page)

### 💮 🗁 RN/MD Review only

Health Education Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>B. Health education services are available to Plan members.</b> 22 CCR §53851; 28 CCR 1300.67 fi} ↔					
Health education materials and Plan-specific resource information are: 1) readily accessible on site, or are made available upon request,	1)	1)	1)	1	
2) applicable to the practice and population served on site,	2)	2)	2)	1	
3) available in threshold languages identified for county and/or area of site location.	3)	3)	3)	1	
<b>Comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 3					

Totals

### 💮 🗁 RN/MD Review only

Criteria	VI. Infection Control Reviewer Guidelines
A. Infection control	<b>Deficiencies:</b> All deficiencies related to Infection Control must be addressed in a corrective action plan.
A. Infection control procedures for Standard/Universal precautions are followed.	<ul> <li>Deticiencies: All deficiencies related to Infection Control must be addressed in a corrective action plan.</li> <li>Hand washing facilities: 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 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.</li> <li>Waste disposal container: Contaminated wastes (e.g. dental drapes, band aids, sanitary napkins, soiled disposal diapers) are</li> </ul>
	<ul> <li><u>Isolation procedures</u>: Personnel are able to demonstrate or verbally explain procedure(s) used on site to isolate patients with potentially contagious conditions from other patients. If personnel are unable to demonstrate or explain site-specific isolation procedures will vary from site to site.</li> </ul>
	<u>Note</u> : Infection Control standards are practiced on site to minimize risk of disease transmission. Site personnel are expected to apply the principles of "Standard Precautions" (CDC, 1996), used for all patients regardless of infection status. Standard precautions apply to blood, all body fluids, non-intact skin, and mucous membranes, which are treated as potentially infectious for HIV, HBV or HCV, and other Bloodborne pathogens. "Universal precautions" refer to the OSHA mandated program that requires implementation of work practice controls, engineering controls, Bloodborne pathogen orientation/education, and record keeping in healthcare facilities.

# VI. Infection Control (continued on next page)

😨 🗁 RN/MD Review only

Infection Control Survey Criteria		No	N/A	Wt.	Site Score
<b>A. Infection control procedures for Standard/Universal precautions are followed.</b> 8 CCR §5193; 22 CCR §53230; 29 CFR §1910.1030; Federal Register 1989, §54:23042					
1) Antiseptic hand cleaner and running water are available in exam and/or treatment areas for hand washing.	1)	1)	1)	1	
2) A waste disposal container is available in exam rooms, procedure/treatment rooms and restrooms.		2)	2)	1	
3) Site has procedure for effectively isolating infectious patients with potential communicable conditions.	3)	3)	3)	1	

**Comments:** Write comments for all "No" (0 points) and "N/A" scores.

Total points possible: 3

#### 😥 🗁 RN/MD VI. Infection Control Reviewer Guidelines – B. Site is compliant with OSHA Bloodborne Pathogens Standard and Waste Management Act.

Deficiencies: All deficiencies related to Infection Control must be addressed in a corrective action plan.

**Personal Protective Equipment (PPE):** PPE for protection against Bloodborne 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.

**Blood and Other Potentially Infectious Materials (OPIM):** OPIM are all human body fluids, any unfixed tissue or organ (other than intact skin) from a human (living or dead), and HIV or HBV-containing blood, cells, tissue, organs, cultures, medium or solutions. Containers for blood and OPIM are closable, leak proof, and labeled and/or color-coded. Double bagging is required only if leakage is possible.

**Labels:** 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.

**Needlestick Safety:** Contaminated sharps are discarded immediately. Sharps containers are located close to the immediate area where sharps are used, and are inaccessible to unauthorized persons. Sharps are not bent, removed from a syringe, or recapped except by using 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 (8CCR, Section 5193). Security of portable containers in patient care areas is maintained at all times. Any device capable of cutting or piercing (e.g. syringes, hypodermic needles, needleless devices, blades, broken glass, slides, vials) are placed in a closable, puncture-resistant, labeled, leak-proof container. If these requirements are met, containers on hand is adequate to ensure routine change-out when filled. **Sharps Injury documentation:** Site has a method in place to document sharps injuries. Date, time, description of exposure incident, sharp type/brand, follow-up care is documented within 14 days of injury incident.

<u>Contaminated Laundry</u>: Contaminated laundry (soiled with blood/OPIM) is laundered by a commercial laundry service, or a washer and dryer on site. Contaminated laundry should not contain sharps, and when transported, should have the appropriate warning label (see Labels bullet above). Manufacturer's guidelines are followed to decontaminate and launder reusable protective clothing. Laundry requirements are "not applicable" if only disposable patient gowns and PPE are used on site.

**Regulated Waste storage:** Regulated wastes include: 1) **Biohazarous 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. Regulated waste is contained separately from other wastes (e.g., contaminated wastes)\* *and* placed in red biohazarous bags with Biohazard label, and stored in a closed container that is not accessible to unauthorized persons. If stored outside the office, a lock secures the entry door, gate or receptacle lid, and posted warning sign(s) in English *and* Spanish are visible for 25-feet: "CAUTION-BIOHAZARDOUS WASTE STORAGE AREA- UNAUTHORIZED PERSONS KEEP OUT" or "CUIDADO-ZONA DE RESIDUOUS-BIOLOGICOS PELIGOROS-PROHIBIDA LE ENTRADA A PERSONAS NO AUTHORIZADAS." Signs prior to the passage of the Medical Waste Act are permitted for the "life" of the sign.

**Medical Waste disposal:** Medical wastes are hauled to a permitted offsite medical waste treatment facility, transfer station, or other registered generator by a registered hazardous waste transporter *OR* person with an approved limited-quantity hauling exemption granted by the CDPH Division of Drinking Water and Environmental Management Branch. Limited-quantity hauling exemptions are renewed annually. A medical waste tracking document that includes the name of the person transporting, number of waste containers, 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. Medical Waste (including sharps) transported by mail are only acceptable through vendors on the approved CDPH Mail Back Service List at: www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/SharpsMailBackList.pdf .

Ref: CDPH Medical Waste Management Program: www.cdph.ca.gov/certlic/medicalwaste/Pages/Contact.aspx or www.cdph.ca.gov/certlic/medicalwaste/Pages/default.aspx. The full CA Medical Waste Management Act (H&SC 117600-11836) is at www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/MedicalWasteManagementAct.pdf

\*<u>Note</u>: Contaminated wastes include materials soiled with blood during the course of 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.

## VI. Infection Control (continued on next page)

### 👧 🗁 RN/MD Review only

Infection Control Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>B.</b> Site is compliant with OSHA Bloodborne Pathogens Standard and Waste Management Act. 8 CCR §5193 (Cal OSHA Health Care Worker Needlestick Prevention Act, 1999); H& S Code, §117600-118360 (CA Medical Waste Management Act, 1997); 29 CFR §1910.1030.					
1) <u>Personal Protective Equipment is readily available for staff use</u> .	1)	1)	1)	2	
2) <u>Needlestick safety precautions are practiced on site</u> .	2)	2)	2)	2	
3) All sharp injury incidents are documented.	3)	3)	3)	1	
4) <u>Blood. other potentially infectious materials and Regulated Wastes are placed in appropriate</u> <u>leak proof. labeled containers for collection. handling. processing. storage. transport or shipping</u> .	4)	4)	4)	2	
5) Biohazarous (non-sharp) wastes are contained separate from other trash/waste.	5)	5)	5)	1	
6) Contaminated laundry is laundered at the workplace or by a commercial laundry service.	6)	6)	6)	1	
7) Storage areas for regulated medical wastes are maintained secure and inaccessible to unauthorized persons.	7)	7)	7)	1	
8) Transportation of regulated medical wastes is only by a registered hazardous waste hauler or by a person with an approved limited-quantity exemption.	8)	8)	8)	1	

Comments: Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 11

### 🕵 🗁 RN/MD Review only

Criteria	VI. Infection Control Reviewer Guidelines
C. Contaminated surfaces are decontaminated according	<b>Deficiencies:</b> All deficiencies related to Infection Control must be addressed in a corrective action plan.
to Cal-OSHA standards. $\textcircled{2}$	<b><u>Routine Decontamination</u></b> : Contaminated work surfaces are decontaminated with an appropriate disinfectant (29 CFR 1910.1030). Written "housekeeping" schedules have been established and are followed for regular routine daily cleaning. Staff is able to identify frequency for routine cleaning of surfaces and equipment, the disinfectant used and responsible personnel.
	<b>Spill Procedure</b> : Staff is able to identify procedures for prompt decontamination of blood/body fluid spills, the disinfectant used, and the responsible person(s).
	<b>Disinfectant Products</b> : 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 reconstituted and applied according to manufacturer's guidelines for "decontamination."
	<b><u>10% Bleach Solution</u></b> : 10% bleach solution that is EPA registered, effective against TB, is changed/reconstituted <i>every</i> 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, <i>specific</i> to every bleach product, are followed carefully.
	<b>Note:</b> "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 <u>www.epa.gov/oppad001/chemregindex.htm</u> .

# VI. Infection Control (continued on next page)

### 💮 🗁 RN/MD Review only

Infection Control Survey Criteria		No	N/A	Wt.	Site Score
<b>C. Contaminated surfaces are decontaminated according to Cal-OSHA Standards.</b> 8 CCR §5193; CA H&S Code §118275 fi}					
1) Equipment and work surfaces are appropriately cleaned and decontaminated after contact with blood or other potentially infectious material.		1)	1)	1	
2) Routine cleaning and decontamination of equipment/work surfaces is completed according to site-specific written schedule.		2)	2)	1	
Disinfectant solutions used on site are: 3) approved by the Environmental Protection Agency (EPA).		3)	3)	1	
4) effective in killing HIV/HBV/TB.		4)	4)	1	
5) used according to product label for desired effect.	5)	5)	5)	1	

Comments: Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 5

### 😥 🗁 RN/MD Review only

Criteria	VI. Infection Control Reviewer Guidelines				
D. Reusable medical	<b>Deficiencies:</b> All deficiencies related to Infection Control must be addressed in a corrective action plan.				
instruments are properly sterilized after each use.	<u>Cleaning prior to sterilization</u> : 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. Personnel are able to demonstrate or verbally explain procedure(s) used for cleaning prior to sterilization, and to locate written directions on site.				
	<u>Cold/chemical sterilization</u> : 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 are available on site to staff.				
	<u>Autoclave/steam sterilization</u> : 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.				
	<u>Autoclave maintenance</u> : 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.				
	<b>Spore testing</b> : Autoclave spore testing is performed <i>at least monthly</i> , 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: <i>report</i> problem, <i>repair</i> autoclave, <i>retrieve</i> all instruments sterilized since last negative spore test, <i>re-test</i> autoclave and <i>re-sterilize</i> retrieved instruments ( <b>R</b> eport/ <b>R</b> epair/ <b>R</b> etrieve/ <b>R</b> etest/ <b>R</b> e-sterilize). Note: Sterilization methods include autoclaves (steam under pressure), Ethylene Oxide (EO) gas sterilizer, dry-heat sterilizer, and liquid chemical sterilants. 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.				
	Sterile 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). 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. Maintenance of 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.				

# VI. Infection Control (continued from previous page)

👧 🗁 RN/MD Review only

Infection Control Survey Criteria	Yes	No	N/A	Wt.	Site Score
<b>D. Reusable medical instruments are properly sterilized after each use.</b> 22 CCR §53230, §53856 fi} •					
1) Written site-specific policy/procedures or Manufacturer's Instructions for instrument/equipment sterilization are available to staff.		1)	1)	1	
Staff adheres to site-specific policy <u>and/or</u> manufacturer/product label directions for the following procedures: 2) Cleaning reusable instruments/equipment prior to sterilization		2)	2)	1	
3) Cold chemical sterilization		3)	3)	1	
4) Autoclave/steam sterilization		4)	4)	1	
5) Autoclave maintenance		5)	5)	1	
6) Spore testing of autoclave/steam sterilizer with documented results (at least monthly)	6)	6)	6)	2	
7) Sterilized packages are labeled with sterilization date and load identification information.	7)	7)	7)	1	
<b>comments:</b> Write comments for all "No" (0 points) and "N/A" scores. Total points possible: 8					
Totals					