Criteria	Reviewer Guidelines
Facility Review Face Page	Review Date: Complete by entering the date or dates of review. Last CHDP Review Date and Results: Enter the date that a prior review was completed and the percent compliance. Provider Name: Enter legal name of Provider for the facility being reviewed. Address: Enter the address of the facility being reviewed. Telephone Number: Enter the primary phone number of the office. Fax: Enter the fax number of the office. Contact Person/Title: Enter the first and last name and the title of the person with whom the visit was arranged. This should be the person designated by the Provider as the primary contact. Clinicians on Site: Enter first and last name(s) and license title (MD, PA, NP) of CHDP physician(s), physician assistants, nurse practitioners performing CHDP health assessment(s) at the site. (Attach additional sheet with names if necessary) Reviewer/Title: Enter first and last names and license title of the reviewer(s) conducting the facility review. CHDP Provider: Place a mark in the space that designates Comprehensive Care versus Health Assessment Only, as defined on page 5-2 of the CHDP Local Program Guidance Manual. Visit Purpose: Indicate the purpose for this site visit to the facility. Check only one of the following. • Initial Full Scope: Visit to a new Provider Applicant, not previously enrolled. • Periodic Full scope: Provider Applicant enrolled and in the process of 3 yr. Recertification review. • Monitoring/Focused Review: Additional review as the result of complaints or local program monitoring. • Follow Up: Previous site visit observed and reported problem areas or potential problems were identified through review of documents, or CHDP received a client complaint. History of Other DHCS Certifications: If known, list other site visits provider has had. Provider Types at Site: Check all types of licensed providers doing CHDP exams at this site. Office/Clinic Type: Indicate the type of CHDP provider for this Provider that corresponds with the range of provider types in CHDP. Select the type that pertains to this site. Score: Enter points given divided by total point to obtain decimal score. Multiply decimal score X 100 to obtain compliance rate and enter percent compliance in the space provided. Compliance Threshold: Note measures taken as a result of compliance rate outcome. Approval Status: Identify the approval status using the criteria listed in the Facility Review Tool Instructions and check one.

<table>
<tr><th colspan="2">Criteria</th><th colspan="3">Reviewer Guidelines</th></tr>
<tr><td rowspan="6">1. Personnel

A. Professional licenses and certifications are current for all health assessment providers at this provider site.</td><td>Medical Professional</td><td>License/Certification</td><td>Issuing Agency</td></tr>
<tr><td>Physician/Surgeon (MD)</td><td>Physician/ Surgeon License</td><td>Medical Board of CA</td></tr>
<tr><td>Doctor of Osteopathy (DO)</td><td>Physician’s & Surgeon’s License</td><td>Osteopathic Medical Board of CA</td></tr>
<tr><td>Physician Assistant (PA)</td><td>PA License</td><td>Physician Assistant Examining Committee/Medical Board of CA</td></tr>
<tr><td>Nurse Practitioner (NP)</td><td>RN License and NP License
NP Furnishing Certificate (as applicable)</td><td>CA Board of Registered Nursing
CA Board of Registered Nursing</td></tr>
<tr><td colspan="3">This information can be found at: <u>http://www2.dca.ca.gov/pls/wllpub/wllquery$.startup</u>

<u>Note:</u> All medical professional California licenses and certifications must be current and issued from the appropriate agency. The above listed medical professional licenses and certificates are issued for practice in California. Any license/certification that has been approved during the current re/credentialing process need not be re-checked during the site review. Any licenses or certifications not included in the re/credentialing process must be checked for current status as part of the site review process.</td></tr>
<tr><td colspan="2">B. Health care personnel are properly identified.</td><td colspan="3">A health care practitioner shall disclose, while working, his or her name and practitioner’s license status, as granted by the State of California, on a name tag at least 18-point type. “Health care practitioner” means any person who engages in acts that are the subject of licensure or regulation under the California Business and Professional Code. A health care practitioner in a practice or an office, whose license is prominently displayed, may opt not to wear a nametag. In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title “nurse” in reference to himself or herself, in any capacity, except for an individual who is a registered nurse, or a licensed vocational nurse. Although staff model sites or sites with centralized personnel departments are not required to keep documents or copies on site for reviewers, copies of documents and/or lists of currently certified or credentialed personnel must be readily available, if needed. (See http://www.medbd.ca.gov/licensee/notices_to_consumers.html#notice regarding prominent display of business and professional licensure).

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

C. Staff are qualified and trained and have access to information to ensure a safe office environment.	Medications: Unlicensed staff (e.g. medical assistant) has evidence of appropriate training and supervision in all medication administration methods performed within their scope of work. Administration of medications by a medical assistant (MA) means the direct application of pre-measured medications orally, sublingually, topically, vaginally or rectally, by providing a single dose to a patient for immediate self-administration, by inhalation or by simple injection. In every instance, prior to administration of medication by the MA, a licensed physician or podiatrist, or another person authorized by law to do so shall verify the correct medication and dosage. The pre-labeled medication container must be shown to the licensed person prior to administration. A MA may administer injections or scheduled drugs, including narcotic medications, **only** if the dosage is verified and the injection is intradermal, subcutaneous, or intramuscular. All medications administered by an MA must be specifically authorized by the supervising physician. Specific authorization means a specific written order or standing order prepared by the supervising physician. MAs may not place an intravenous (IV) needle, start or disconnect the IV infusion tube, administer medications or injections into an IV line, or administer anesthesia. Medical Equipment: All personnel are appropriately trained in the proper utilization of all medical equipment they are expected to operate in their scope of work. For any medical equipment kept on site, there are personnel on site who are qualified and/or trained to use equipment properly. (For example, audiometric testing, vision screening, obtaining BMI percentile, if there is an emergency "Crash" cart/kit on site, personnel on site are qualified and properly trained in the correct use of the equipment). Reviewers may interview site personnel regarding the appropriate use of equipment and/or request demonstrated use of equipment, as appropriate. Unlicensed personnel: MAs are unlicensed health personnel, at least 18 years of age, who perform basic administrative, clerical, and non-invasive routine technical supportive services under the supervision of a licensed physician, surgeon or podiatrist in a medical office or clinic setting. Supervision means that licensed physician must be physically present in the treatment facility during the performance of authorized procedures by the medical assistant. In order to administer medications by intramuscular, subcutaneous and intradermal injection, to perform skin tests or venipuncture for the purpose of withdrawing blood, a medical assistant must have completed at least the minimum amount of training hours established in Title 16, section 1366.1. 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 supervising physician is responsible for determining the training content and ascertaining proficiency of the medical assistant. Medical Assistant (MA) training documentation maintained on site must include the following: A) Diploma or certification from an accredited training program/school, ***or*** B) Letter/statement from the current supervising physician that certifies in writing: date, location, content, and duration of training, demonstrated proficiency to perform current assigned scope of work, and signature. C) Evidence of training or attendance at state audiometric training and vision training is documented. **Note:** Personnel on site must be qualified for their responsibilities and adequately trained for their scope of work. Site staff should have a general understanding of the systems/processes in place, appropriate supervision and knowledge of the available sources of information on site. Non-Physician Medical Practitioners NMP: Nurse Practitioners (NP): Nurse practitioners are prepared through education and experience to provide primary care and to perform advanced procedures. The extent of required supervision must be specified in the Standardized Procedures. Physician Assistants (PA): Every PA is required to have the following documents: 1) Delegation of Services Agreement: This written agreement between the supervising physician and PA defining specific procedures identified in practice protocols or specifically authorized by the supervising physician must be dated and signed by both individuals. 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.

Criteria	Reviewer Guidelines
1. Personnel **C. All staff members are qualified and trained for assigned responsibilities.**	2) Approved Supervising Physician's Responsibility for Supervision of Physician Assistants: This written document, signed by the supervising physician defines supervision responsibilities and methods required by Title 16, section 1399.545 of the Physician Assistant Regulations. The following procedures must be identified: a) Transport and back-up procedures for immediate care of patients in need of emergency care that is beyond the PA's scope of practice when the supervising physician is not on the premises. b) One or more of the following methods for performing medical record review by the supervising physician: • examination of patient by supervising physician the same day as care is given by the PA • review/audit and countersign all medical records of the PA within 30 days of the encounter • review/audit and countersign medical records of at least 5% of patients managed by the PA under any protocols adopted by the supervising MD and PA • other methods approved in advance by the Physicians Assistant Examining Committee. c) Responsibility to review, countersign and date within 7 days the medical record of any patient cared for by a PA for whom the physician's prescription was transmitted or carried out. d) Responsibility to review, countersign and date medical records of any patient cared for by a PA operating under interim approval within 7 days if physician was on the premises at the time and within 48 hours if physician was not on the premises. e) Responsibility of the PA to enter the name of his/her approved supervising physician who is responsible for the patient on the medical record, chart or written order each time the PA provides care and enters his/her name, signature, initials or computer code. When the PA transmits an oral order, the supervising physician's name must also be stated. **Note:** 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. Supervision of Non-Physician Medical Practitioners (NPMP): Supervising physician: "Supervising physician" means a physician and 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. Physicians must comply with all current and/or revised requirements established by the Medical Board of California for supervising physician assistants. Supervision of physician assistants: "Supervision" means that a licensed physician and surgeon oversees the activities of, and accepts responsibility for, the medical services rendered by a physician assistant. The Supervising Physician holds ultimate responsibility for the practice of each supervised non-physician medical practitioner. The ratio of physician supervising to number of NPMPs is not to exceed established ratios in any combination of the following: 1:4 Nurse Practitioners 1:4 Physician Assistants The designated supervising or back-up physician is to be available in person or by electronic communication at all times when a NPMP is caring for clients.

Criteria	Reviewer Guidelines
1. Personnel **C. All staff members are qualified and trained for assigned responsibilities.**	There are written policies and procedures or other written documentation for: 1. Infection control/universal precautions 2. Bloodborne pathogens exposure prevention 3. Biohazardous waste management 4. Disaster preparedness for emergency nonmedical events (e.g., workplace violence) 5. Child/elder/domestic violence abuse and mandated reporting 6. Fire prevention/safety 7. Implementation of HIPAA requirements (e.g., client confidentiality, release of information) 8. Sensitive services/minor's rights 9. Consent for treatment Acceptable evidence of training shall include documentation of in-service training, which may include educational curriculum/lesson plans, and training attendance records. Staff is able to locate procedures on site, and can explain how to use information. There is written documentation of orientation of new staff within three months of hire, and annual training of existing staff on the following: 1. Infection control/universal precautions 2. Bloodborne pathogens exposure prevention 3. Biohazardous waste management 4. Disaster preparedness for emergency nonmedical events (e.g., workplace violence) 5. Child/elder/domestic violence abuse and mandated reporting 6. Fire prevention/safety 7. Implementation of HIPAA requirements (e.g., client confidentiality, release of information) 8. Sensitive services/minor's rights 9. Consent for treatment 10. CHDP training in anthropometric measurements, including obtaining Body Mass Index (BMI) percentile. 11. Medical emergency staff training and participation in mock drills (Office BLS procedures)* 12. Completion and utilization of CHDP training in audiometric screening, or equivalent upon approval of local program. (At least every four years) 13. Completion and utilization of CHDP training in vision screening, or equivalent upon approval of local program. (At least every four years) *Adapted from American Academy of Pediatrics, Committee on Pediatric Emergency Medicine, "Preparation for Emergencies in the Office of Pediatricians and Pediatric Primary Care Providers". Pediatrics, Vol. 120 No.1 July 2007 and as Excerpted from Title 22, California Code of Regulations (CCR), Section 51056(b).

Criteria	Reviewer Guidelines
2. Office Management **A. Physician coverage is available 24 hours a day, 7 days a week.**	Current clinic office hours are posted within the office or readily available upon request. When a physician is not on site during regular office hours, site staff is able to contact the physician at all times by telephone, cell phone, pager, etc. Personnel is knowledgeable about scheduled physician coverage during office hours and for after-hours urgent and emergent physician coverage 24 hours a day, 7 days per week, to provide follow up care. Current resource information is available to site personnel. Note: This is a requirement for Comprehensive Care entities/examiners only. Health Assessment Only entities/examiners must refer clients to medical and dental homes that provide this coverage. Telephone triage is the system for managing telephone callers during and after office hours. In addition to the physician, only appropriately licensed medical personnel such as a NP, RN, or PA shall handle emergency, urgent, and medical advice/triage telephone calls. **Note:** The review of office management evaluates whether effective clinic office systems are in place and whether site personnel appropriately use established site-specific procedures. The primary objective of effective clinic office management is to support and enhance the provision of appropriate, coordinated health care services.
B. Readily available health care services shall be provided.	There is a process/system in place on site that provides clients with timely access to appointments for routine care, urgent care, prenatal care, initial and periodic pediatric health assessments/immunizations, initial health assessments, specialty care and emergency care. **Note:** the Board of Vocational Nurse and Psychiatric Technician Examiners have determined that the Licensed Vocational Nurse Practice Act does not permit the LVN to perform triage independently. Licensed vocational nurses may perform that part of the triage process that includes observation and data collection relative to basic physical assessment. Licensed vocational nurses may not perform that part of the triage process that includes independent evaluation, interpretation of data, and determination of treatment priorities and levels of care. Unlicensed personnel, such as medical assistants, may provide patient information and instructions only as authorized by the physician (Title 16, §1366(b).
C. All Provider sites provide interpreter services for limited English proficient clients either through telephone language services or interpreters on-site.	All provider sites provide 24-hour interpreter services for all clients either through telephone language services or interpreters on site. Any 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. A client's request for or refusal of language/interpreter services must be documented in the client's medical record. **Note:** 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.

Criteria	Reviewer Guidelines
2. Office Management **D. Referral/ consultative services are handled according to established site-specific procedures.**	There is a process/system in place on site to make timely referrals both internally and externally, track outstanding referrals, complete review reports, provide follow-up care, and file reports in medical records. Referral resource information is readily available on site for use by provider and site personnel. Systems will vary per site. However, personnel must effectively utilize established site specific procedures to ensure timely provision of referral/consultative services and follow-up care. Current Medi-Cal provider manual, CHDP Health Assessment Guidelines, and CHDP Provider Manual or other manuals are available for reference. Give points if they have evidence that the CHDP Provider Manual is on-line. The policy should include a notation that missed and/or canceled appointments, contact attempts, and results of referral(s) are documented in the client's medical record.
E. Medical records are available for the Provider at each scheduled client encounter.	A system is in place and utilized by site personnel to effectively coordinate the availability of medical records, including outpatient, inpatient, referral services, and significant telephone consultations, for client encounters.
F. Confidentiality of personal medical information is protected according to State and Federal Guidelines, including HIPAA.	Privacy: Clients have the right to privacy for dressing/undressing, physical examination and medical consultation. Practices are in place to safeguard client privacy. Because dressing areas and examination room configurations vary greatly, reviewers will make site-specific determinations. New patients are given practice privacy policies. Confidentiality: Personnel follow site office policy/procedures for maintaining confidentiality of individual patient information. Clients or their conditions are not discussed in front of other clients or visitors. Individual client information is not displayed or left unattended in reception and/or client flow areas. Electronic records: If an electronic record-keeping system is used, procedures must be in place to ensure client confidentiality, prevent unauthorized access, authenticate electronic signatures, and maintain computer systems. Security protection must include an off-site backup storage system, an image mechanism with the ability to copy documents, a mechanism to ensure recorded input unalterable, and file recovery procedures. Confidentiality protection may also include use of encryption, detailed user access controls, transaction logs, and blinded files. Record release: Medical records cannot be released without written, signed consent from the client or client'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.

Criteria	Reviewer Guidelines
3. Health Education Services **A. Health education services are available to clients.**	Health education services: These may include provider, or community sponsored services such as individual instruction, family counseling, group classes and/or other health educational program. Health education materials: These may include written or electronic 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, Anticipatory Guidance, Nutrition, Physical Activity, STI/HIV Prevention, Family Planning, Asthma, Hypertension, Diabetes, etc. Materials may be located in an accessible area on site such as exam or waiting room, or provided by clinic staff to clients upon request. Threshold languages: Informing materials and interpreter services must be provided in identified threshold and concentration standard languages. **Note:** Threshold languages are the primary languages spoken by Limited English Proficient (LEP) population groups residing in a county. A numeric threshold of 3,000 eligible LEP Medi-Cal beneficiaries or a concentration standard of 1,000 residing in a single ZIP code or 1,500 in two contiguous ZIP codes establishes the threshold languages identified by the Department of Health Care Services for each county. Local resource list can be developed by local CHDP program or Public Health. It should include information on referrals to Medi-Cal/Healthy Families and WIC as well as other Public Health Programs. Healthy Families applications available through MRMIB at www.mrmib.ca.gov

Criteria	Reviewer Guidelines
4. Site Access **A. The provider site shows evidence of safety and fire precautions.**	*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. *Exits: Exit doorways are unobstructed and clearly marked by a readily visible "Exit" sign. All electrical outlets have an intact wall faceplate. Fire Fighting/Protection Equipment: There is fire fighting/protection equipment in an accessible location on site at all times. An accessible location is one that is reachable by personnel standing on the floor, or other permanent working area, without the need to locate/retrieve step stool, ladder or other assistive devices. At least one of the following types of fire safety equipment is on site: 1) Smoke Detector with intact, working batteries 2) Fire Alarm Device with code and reporting instructions posted conspicuously at phones and employee entrances 3) Automatic Sprinkler System with sufficient clearance (10-in.) between sprinkler heads and stored materials 4) Fire Extinguisher in an accessible location that displays readiness indicators or has an attached current dated inspection tag See the following website for additional information: http://www.dir.ca.gov/title8/6519.html Child Safety Precautions: The environment reflects understanding of child safety issues with electrical outlets accessible to children covered, cords to window coverings out of the reach of small children, cabinet locks available for those areas where children pass through, and live plants are out of the reach of children. *American's With Disabilities Act (ADA): See Attachment to Reviewer Guidelines – Access/Safety related to ADA
B. The site ensures the following are in place.	Emergency Care: During business hours providers shall be prepared to provide emergency services for the management of emergency medical conditions that occur on site until the emergent situation is stabilized and/or treatment is initiated by the local 911 Emergency Medical Service (EMS) system. 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. Emergency equipment and education, appropriate to patient population and conditions treated, are available on site and in an accessible location. An accessible location is one that is reachable by personnel standing on the floor, or other permanent working area, without the need to locate/retrieve step stool, ladder or other assistive devices. **Emergency medical equipment: Minimum emergency equipment is available on site to: 1) establish and maintain a patent/open airway, and 2) manage anaphylactic reaction. A site's proximity to emergency care facilities may be considered when evaluating site specific, medical emergency procedures. Site must have a clearly established system for providing basic emergency care on site until the local Emergency Medical System has taken over care/treatment. **Airway management suitable for infants, children, and adolescents: Without the ability to adequately control the airway, all other interventions are futile. Minimum airway control equipment includes an oxygen delivery system or portable oxygen tank, suction device- tonsil tips and/or bulb syringe, oropharyngeal airways (sizes 00 through 5 recommended) appropriate for population served, nasal cannulas, bag-valve masks (infant, child and adult), oxygen face masks (infant, child and adult), Nebulizer (or metered-dose inhaler with spacer/ mask) Various sizes of airway devices are on site and appropriate to client population within the practice. Portable oxygen tanks are maintained at least ¾ full. There is a method/system in place for oxygen tank replacement. If oxygen tanks are less than ¾ full at time of site visit, site has a back up method for supplying oxygen if needed and a scheduled plan for tank replacement. Oxygen tubing can be attached, not necessarily connected to oxygen tank. Demonstrates proficiency in handling oxygen equipment. Anaphylactic reaction management: Severe allergic reaction can cause urticaria (hives), hypotension, bronchospasm, wheezing and pulmonary edema. Minimum equipment includes epinephrine (subcutaneous use), albuterol for inhalation (metered-dose inhaler with spacer or mask may be substituted), tuberculin syringes, alcohol wipes, splints and sterile dressings There is a current medication administration reference (e.g., medication dosage chart) available for readily identifying the correct medication dosages (e.g., adult, pediatric, infant, etc.). Dosages for emergency medication can be determined by the local medical director. Local Poison Control Number: The number is posted and visible for personnel. See www.calpoison.org for most current information. A written Emergency Plan is posted and appropriate staff has current CPR certification. One certified staff must be on site at all times. The emergency "Crash" cart/kit on site has contents that are appropriately sealed and within the expiration dates posted on label/seal. Site personnel are trained and can demonstrate knowledge and correct use of all emergency medical equipment kept on site. **Emergency equipment should be appropriate to population served.

Criteria	Reviewer Guidelines
5. Infection Control/ Lab **A. (Laboratory) Site operates in compliance with Clinical Laboratory (CLIA) regulations.**	CLIA Certificates: All clinics/offices performing laboratory testing for assessment of human health or diagnosis, prevention, or treatment of disease must have a current, unrevoked, unsuspended site-specific* Clinical Laboratory Improvement Amendments (CLIA) certificate, or evidence of renewal.) All places that perform tests or examinations on human biological specimens derived from the human body are, by definition, "laboratories" under State and Federal law. Therefore, laboratories may exist at locations such as nurses' stations within hospitals, clinics, surgical centers, physician offices, and health fairs. A copy of an original, certificate or renewal receipt is acceptable. CLIA Certificates on site may include one/more of the following: A) Certificate of Waiver: Site is able to perform only exempt waived tests. B) Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists, or mid-level practitioners are able to perform PPM procedures and waived tests. C) Certificate of registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations is determined by survey. D) Certificate of Compliance: Lab has been surveyed and found in compliance with all applicable CLIA requirements. E) Certificate of Accreditation: Lab is accredited by an accreditation organization approved by the Centers for Medicare and Medicaid Services formerly, Health Care Financing Administration (HCFA). Waived tests: Sites that perform only waived tests must obtain a CLIA Certificate of Waiver. While there are no specific CLIA regulations that apply to the performance of waived tests, following the test manufacturer's instructions is required. Laboratories with certificates of waiver may not be routinely inspected. However, they may be inspected as part of complaint investigations and on a random basis to determine whether only waived tests are being performed. Moderate and High complexity tests: All 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. For these categories the CLIA regulations list specific requirements for laboratory proficiency testing, client test management, quality control, quality assurance, personnel, and inspections. *For exceptions to "site-specific" requirement, see CLIA Regulations Subpart B – Certificate of Waiver; Section 493.35, (b) Exceptions. **Note:** the current listing of waived tests may be obtained at: www.fda.gov/cdrh/clia/testswaived.html. For questions regarding CLIA certification, laboratory licensing, and personnel, call CA DHCS Laboratory Field Services at (213) 620-6160.
B. CHDP Tests/ Lab Equipment **C/D. Infection control procedures for standard/ universal precautions are followed.**	Laboratory equipment: All equipment used to measure or assess client health status/condition is adequately maintained according to the specified manufacturer's guidelines for the equipment, or is serviced annually by a qualified technician. Process in place to check expiration dates and dispose of expired laboratory test supplies, and no expired laboratory test supplies are present. Maintains laboratory supplies/equipment clean and accessible only to staff. Specialized equipment includes, but is not limited to hemoglobinometer, centrifuge, etc. Infection Control: Procedures must be demonstrated in preventing infection transmissions among clients as well as personnel. Standard/Universal Precautions: Site personnel practice the approach to infection control whereby all human blood and body fluids are treated as potentially infectious materials for HIV, HBV or HCV, and other bloodborne pathogens. Hand Washing Facilities: There must be an adequate supply of running potable water, soap and single use towels or hot drying machines. Acceptable handwashing facilities may be available in the exam room and/or utility room. If facilities are not available in the immediate client exam areas, staff must demonstrate methods used on site to provide infection control "barriers" to prevent contamination of door handles, surfaces, etc. until handwashing can be performed. Although foot-operated pedals or 4-6 inch wing-type faucet handles may be optimal in treatment/exam room areas, do not deduct points if not on site. Antiseptic Hand Cleaner: For general client care, a plain, non-antimicrobial soap is appropriate in any convenient form, such as bar, leaflets, liquid, or powder (Association for Professionals in Infection Control and Epidemiology, Inc., 1995). Hand antisepsis, by use of soap or detergent products containing antimicrobial agents or alcohol-based antiseptic hand rubs, is recommended before contact with the patient, when persistent antimicrobial activity on the hands is desired, or to reduce numbers of resident skin flora in addition to transient microorganisms. Hand wash products must be stored/dispensed to prevent contamination or infection. Sharps containers are labeled and located in area where sharps are used and are accessible only to staff responsible for the use of sharps. **Note:** The principles of infection control are established to minimize the risk of disease transmission to clients, providers and the provider's employees. The purpose of hand washing is to remove dirt, organic material and transient microorganisms. Both plain and antiseptic hand wash products can become contaminated or support the growth of microorganisms if not stored or dispensed properly. Reviewers should note whether hand wash products are maintained appropriately to prevent contamination.

Criteria	Reviewer Guidelines
5. Infection Control/ Lab **B. CHDP Tests/ Lab Equipment** **C/D. Infection control procedures for standard/ universal precautions are followed.**	Safety practices on site are followed in accordance with current/updated CAL-OSHA standards. Hazardous substances labeling: 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 secondary containers into which hazardous substances are transferred or prepared contain labels that provide the following information: ▪ Identity of hazardous substance. ▪ Description of hazard warning: can be words, pictures, symbols. ▪ Date of preparation or transfer. **Note:** 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. All portable containers of hazardous chemicals require labeling. Exception: Labeling is not required for portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the individual who performs the transfer. All other portable containers and usage require labeling.
6. Clinical Services **A. Immunizations (Drugs/ Immunobio-logics) are administered and stored according to State/Federal standards.**	Vaccines for Children (VFC) Provider/Participant: Business Entity or Examiner must participate in the VFC program. Expired Immunization: Inquire into how the office checks for expired immunizations, how often, and what they do with vaccine that is close to expiring or has expired. Check a few random vaccines for expiration dates. Provider must contact VFC for guidelines for returning expired or close to expired vaccine. Clean Area: Ask provider office to show reviewer where vaccines are prepared. Office personnel should be able to explain how the area is kept clean. A drug or device shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or of it has been prepared, packed or held under unsanitary conditions (21USC, Section 351). Equipment: Reviewer should assess for various syringes, if safety needles are being utilized and how they are stored. Needle type should be appropriate for type of injection. Provider should have 3 cc and tb syringes and 5/8" and 1" needles. Clean Storage: Assess storage area. No food, lab specimens, cleaning supplies or other items that may cause contamination should be stored with the vaccine. Drugs must be stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug product are not affected (21CFR, section 211.142). A drug is considered "adulterated" if it has been held under unsanitary conditions that may have been contaminated with filth, or rendered injurious to health (21USC, Section 351). Safe Storage: Assess that immunizations, needles and syringes are not accessible by patients or children. It is acceptable if storage and preparation area is away from clinic traffic. Also acceptable if cabinets, drawers or doors are locked. Vaccine Immunization Statements (VISs): Office personnel should be able to explain that a VIS is given with each vaccine administered, in the appropriate language and how it is documented in the medical record. Since 1994, the National Childhood Vaccine Injury Act, Section 2126 of the Public Health Services Act, mandates that parents/guardians or adult clients be informed before vaccinations are administered. See http://www.immunize.org/catg.d/p2027.pdf for most current information. Health care providers must have available as hard copy or electronically, the most recent VIS, in appropriate threshold languages, to clients prior to each vaccination dose. The date the VIS was given and the publication date of the VIS must be documented in the client's medical record. Reviewers shall interview personnel about standard practices on site regarding VIS distribution. The most current VISs are available from VFC, state immunization website or your local health departments. They may also be downloaded from the following website at: www.immunize.org/vis/ or by calling the CDC Immunization Hotline at 800-CDC-INFO.

Criteria	Reviewer Guidelines
6. Clinical Services **A. Immunizations/ Drugs/Immuno biologics) are administered and stored according to State/Federal standards.***	Immunobiologics: Has current schedules and immunizations or combinations as recommended by ACIP. For a list of current vaccines available, refer to the CHDP Provider Manual. Check refrigerator and freezer temperatures manually twice a day, including offices that have alarmed, continuous, automatic, temperature monitoring devices. Have office staff read to the reviewer the temperatures and then reviewer checks accuracy. This gives the reviewer the ability to assess the office staff's ability to read the temperature. Refrigerator must be between 2 to 8 degrees Celsius or 35 to 46 degrees Fahrenheit. Freezer must be –15 degrees Celsius or 5 degrees Fahrenheit or lower. If temperatures are out of range, ask to see temperature logs and refer to VFC Field Representative and/or Immunization Assistance Program (IAP) Coordinator. The California DPH Immunization Branch recommends checking temperatures twice a day, first thing in the morning and last thing at night. Offices should have thermometers that read the minimum and maximum temperatures. These readings are more important to read and document than a single temperature at a point in time. Recommend they talk with VFC and/or IAP for guidelines. Failure to adhere to recommended specifications for storage and handling immunobiologics can make the products impotent. Vaccines must be refrigerated immediately and stored according to specific instructions on the package insert for each vaccine. MMR and varicella must be protected from light at all times, and kept cold. Vaccines should not be stored in the doors of the refrigerator or freezer. Diluent does not need refrigeration if vaccine is administered right after diluent is added. MMR can be stored in the refrigerator or freezer. MMRV and varicella MUST be stored in the freezer. Ask to see the office's written plan for vaccine protection. Review temperature logs of twice a day refrigerator and freezer temperatures. If not done twice a day, inform this is the VFC standard and they must start this practice immediately. Reviewing the log also reveals temperature problems or documentation problems. The freezer must have a separate external door from the refrigerator. No storage permitted in the freezer of dorm style refrigerators. When checking vaccines, observe for PPD solution. Opened bottle should be dated and used within 30 days. Inquire into how other drugs are stored. Narcotics and medications are in a lockable area inaccessible to patients. Follow manufacturer's requirements for storage and administration. *Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed. Washington DC: Public Health Foundation, 2011. http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/table-of-contents.pdf Controlled Substances and Other Medications: See attachment to reviewer guidelines for additional information.
7. Pediatric Preventive Services **A. Preventive health care services and health appraisal examinations are provided on a periodic basis for the detection of asymptomatic diseases.**	Examination table: "Good repair" means clean and well maintained in proper working order. Sites must use a protective barrier to cover exam surface that is changed between patient contact. Thermometer: Plastic strips thermometers (e.g.Tempodots) are not acceptable since they measure skin surface temperature and not body core temperature. Scales: Infant weight scales must be marked and accurate to increments of one (1) ounce or less, and have a capacity of at least 35 pounds. Standing floor scales must be marked and accurate to increments of one-fourth (1/4) pound or less, and have a capacity of at least 400 pounds. Balance beam or electronic scales are appropriate for clinic use. Balance scales must have an adjustment mechanism and zeroing weight to enable routine balancing at zero. Electronic or digital scales must have automatic zeroing and lock in weight features. Digital scales require calibration and may need batteries checked. Spring balance scales (e.g., bathroom scales) are unsatisfactory for clinical use because, over time, the spring counter balance mechanism loses its accuracy. All scales must be routinely maintained according to manufacturer's guidelines and calibrated by a professional vendor at least annually. Use of a standardized weight is satisfactory only for routine scale maintenance, but does not satisfy the need for calibration accuracy through the full range of weight measured by the scale. There must be documentation of professional calibration completed within the last 12 months of the site audit, or if the manufacturer's guidelines are not available on site. Measuring devices: Equipment for measuring stature (length/height) and head circumference must include: A. Equipment for Measuring Length - Recumbent Infant measuring board for ages birth to 2 or 3 years* 1. Measuring tape: The "O" of the tape must be exactly at the base of the headboard a) Attached to a firm, flat, horizontal surface b) Flat, no rounded tape c) Clearly marked to one-eighth inch (1/8") or less d) Made of non-stretchable material 2. Headboard/Stadiometer/Rigid Height Rod a) Rigid and attached to horizontal surface

Criteria	Reviewer Guidelines
7. Pediatric Preventive Services (Continued) **A. Preventive health care services and health appraisal examinations are provided on a periodic basis for the detection of asymptomatic diseases.**	b) Perpendicularly mounted (always at right angle (90°) to the measurement surface c) Minimum 6 inches wide 3. Footboard a) Moveable and non-flexible b) Perpendicularly mounted (always at right angle (90°) to the measurement surface c) Minimum 6 inches wide B. Equipment for Measuring Height – Standing Measuring board for ages 2 and older** 1. Measuring tape: The "O" of the tape must be exactly at foot level for standing measurement. a) Attached to a firm, flat, vertical surface (entire tape mounted on a board or attached to a wall without floor molding) b) Flat, no rounded tape c) Clearly marked to one-eighth inch (1/8") or less d) Made of non-stretchable material 2. Headboard/Stadiometer/Rigid Height Rod: a) Moveable and attached to vertical surface b) Perpendicularly mounted (always at right angle (90°) to the measurement surface c) Minimum 2 inches wide *Some children 18 months to 2 years may be exceptions **Some children 18 months to 3 years may be exceptions Head Circumference: A non-stretchable tape measuring device marked to one-eighth (1/8 or 1 mm) or less for measuring head circumference. Basic equipment: Exam gown sizes are appropriate to population served on site. Vision testing: Sites must have both the Snellen and an illiterate eye chart. Vision screening for infants and children from birth to three years of age consists of a red reflex examination, corneal penlight evaluation, and an external eye inspection. The use of standardized charts, such as HOTV, LEA or equivalent charts, for children age three to five years; Snellen or equivalent charts, for children age six years and older may be used. "Heel" lines must be aligned with center of eye chart at a 20/40-feet or equivalent (e.g., 10/20) line. Eye charts should be in a location with adequate lighting and at height(s) appropriate to use. Disposable eye "occluders", such as Dixie cups or tongue blades with back-to-back stickers, are acceptable. Non-disposable occluders must be cleaned between clients. Vision screening charts are required for CHDP vision screening. CHDP does not accept vision screening using a machine (e.g. SureSight or Titmus) because there is insufficient information on the accuracy of these devices in children. (See Health Assessment Guidelines, Section 61-2) Hearing Screening: Sites must have a State-approved, pure tone air conduction audiometer. A quiet area to administer the test must be available. Each audiometer must be calibrated annually, be powered by alternating current (AC) powered, and have the minimum ability to: • Produce intensities between 0 and to 80dB • Produce frequencies at 1000, 2000 and 4000Hz (3000Hz optional) • Have a headset with right and left earphones • Be operated manually Refer to the latest program letter for the list of approved audiometers. **Note:** Although client population varies from site-to-site, the screening equipment listed in this section is the standard equipment most often used in performing a physical health screening examination for children and adults.

	Attachment to Reviewer Guidelines
Access/Safety Information related to ADA	Parking: Parking spaces for the persons with physical disabilities are located in close proximity to handicap-accessible building entrances. Each 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 the availability of handicap parking spaces in parking areas or nearby on the street, there must be a plan in place to make program services available to persons with physical disabilities. Ramps: There is a clear and level landing 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 1 ft. rise in 20 ft. of horizontal run. Exit doors: Includes all doors required for access, circulation and use of the building and facilities, such as primary entrances and passageway doors. Width of exit doorways (at least 32-in.) allows for passage clearance of a wheelchair. Furniture and other items do not obstruct exit doorways or interfere with door swing pathway. Elevators: If a site has no passenger elevator, a freight elevator may be used to achieve program accessibility if upgraded so as to be usable by passengers generally and if passageways leading to and from the elevator are well-lit, neat and clean. Clear Floor Space: Clear space in waiting/exam areas is sufficient to accommodate a single, stationary adult wheelchair and occupant. Sanitary Facilities: Restroom and handwashing facilities are accessible to able-bodied and handicapped persons. A restroom that is wheelchair accessible allows sufficient space in toilet area for a wheelchair to enter and permits the door to close. If there are no wheelchair accessible restrooms within the site, reasonable alternative accommodations must be made available. Alternatives may include: grab bars located behind and/or along the sides of toilet with assistance provided by site personnel as needed, use of urinal, bedpan, or bedside commode in private area, wheelchair accessible restroom facilities located in a nearby office and/or shared within a building. For wheelchair-bound persons to safely use a lavatory sink for handwashing, sufficient space underneath the sink is needed for knee clearance. A reasonable alternative may include but is not limited to handwashing items provided when needed by site staff. **Note:** A clear space of at least 30-in. x 48-in. is needed to accommodate an adult wheelchair and occupant. A minimum clear space of 60-in. diameter or square area is needed to turn a wheelchair. Specific measurements are provided for *reference only*. A site/facility includes the walkways, parking lots, and equipment, in addition to the building structure. Site reviewers are ***not*** expected to measure parking areas, pedestrian path of travel walkways and/or building structures on site. Measurements are provided strictly as reference information for the reviewer. 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 individual with disabilities, if the construction or alteration is 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, shall be made so as to ensure that, to the maximum extent feasible, the altered portions of the facility are readily accessible to and useable by individuals with disabilities, including individuals who use wheelchairs (28 CFR 36.402). Sites must meet city, county and state building structure and access ordinances for persons with physical disabilities. 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.

	Attachment to Reviewer Guidelines (continued)
Access/Safety Information related to ADA	Reasonable Portion applies to multi-storied structures and provides exceptions of 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 clients, 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. **Reviewers are <u>not required</u> to measure site areas.** <u>Illumination:</u> Lighting is adequate in client flow working and walking areas such as corridors, walkways, waiting and exam rooms, and restrooms to allow for a safe path of travel. <u>Access Aisle:</u> Accessible pedestrian paths of travel (ramps, corridors, walkways, lobbies, elevators, etc.) between elements (seats, tables, displays, equipment, parking spaces, etc.) shall provide a clear circulation path. Means of egress (escape routes) shall be maintained free of all obstructions or impediments to full instant use of the path of travel in case of fire or other emergency. Building escape routes provide an accessible, unobstructed path of travel for pedestrians and/or wheelchair users at all times when the site is occupied. Cords (including taped cords) or other items are not placed on or across walkway areas. <u>Evacuation Routes:</u> Clearly marked, easy-to-follow escape routes are posted in visible areas, such as hallways, exam rooms and patient waiting areas. <u>Electrical Safety:</u> Electrical cords are in good working condition with no exposed wires, frayed or cracked areas. Cords are not affixed to structures, placed in or across walkways, extended through walls, floors, and ceiling or under doors or floor coverings. Extension cords are not used as a substitute for permanent wiring. Sufficient clearance is maintained around lights and heating units to prevent combustible ignition. If there are no sprinklers, at least one of the following types of fire safety equipment is on site: 1 Smoke Detector with intact, working batteries 2 Fire Alarm Device with code and reporting instructions posted conspicuously at phones and employee entrances 3 Fire Extinguisher in an accessible location that displays readiness indicators or has an attached current dated inspection tag **<u>Note:</u>** Sites must meet city, county and state fire safety and prevention ordinances. 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. **Reviewers are <u>not</u> <u>required</u> to measure building areas.**
Equipment and Medication Management	<u>Medical equipment:</u> All equipment used to measure or assess client health status/condition is adequately maintained according to the specified manufacturer's guidelines for the equipment, <u>or</u> is serviced annually by a qualified technician. Specialized equipment includes, but is not limited to audiometer, scales, etc. <u>Documentation:</u> There is documented evidence that standard operating procedures have been followed for routine inspection/maintenance, calibration, repair of failure or malfunction, testing and cleaning of all specialized equipment. Appropriate written records include calibration or other written logs, work orders, service receipts, dated inspection sticker, etc. <u>Controlled substances:</u> These include all Schedule I, II, III, IV, and V substances listed in the CA Health and Safety Code, Sections 11053-11058. The Control Substances Act (CFR 1301.75) requires that controlled substances are stored separately from other drugs in a securely locked, substantially constructed cabinet. Control substances need not be double locked. Written records must be maintained of inventory list(s) of controlled substances that includes: provider's DEA number, name of medication, original quantity of drug, dose, date, name of client receiving drug, name of authorized person dispensing drug, and number of remaining doses. Personnel with authorized access to controlled substances include physicians, dentists, podiatrists, physician assistants, licensed nurses and pharmacists. <u>Other medications:</u> All drugs to be dispensed are stored in an area that is secured (CA Business and Professions Code, §4051.3). 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. The area shall be secure at all times. Keys to locked storage area shall be available only to staff authorized by the physician to have access (Title 6 CCR, Chapter 2, Division 3, Section 1356.32).

	Attachment to Reviewer Guidelines (continued)
Equipment and Medication Management	Drug labeling: The label for each prescription medication dispensed must include provider's name, client's name, drug name, dose, frequency, route, quantity dispensed, and manufacturer's name and lot number. All pre-filled syringes must be individually labeled with date, medication name, and dosage. Drug distribution: Each clinic that provides drug distribution services shall have written policies and procedures for the safe and effective distribution control, storage, use and disposition of drugs. Drug dispensing: The dispensing of drugs must be in compliance with all applicable State and Federal laws and regulations. "Dispensing" of drugs means the furnishing of drugs or devices directly to a client 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. Drugs can only be dispensed by a physician; pharmacist or other persons (e.g., RNs) lawfully authorized to dispense medications upon the order of a licensed physician or surgeon. Personnel such as medical assistants, office managers, and receptionists cannot dispense drugs. Drugs cannot be offered for sale, charged or billed to Medi-Cal members (Business and Professions Code, Article 13, Section 4193). A record of all drugs dispensed must be entered in the client's medical record. 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. Note: **During business hours, the drawer, cabinet or room containing medications and/or medication supplies may remain unlocked only if there is no access to area by unauthorized persons. Whenever medications and/or medication supplies are unlocked, authorized clinic personnel must remain in the immediate area at all times. At all other times, medications and/or medication supplies must be securely locked.**