

CHAPTER 06 Licensing and Regulations

School-based health centers (SBHCs) must meet various legal and regulatory requirements involving the facility used to deliver clinical services, including the certification of any laboratory services provided in the clinic as well as eligibility for reimbursement under Medi-Cal and other programs. This chapter provides an overview of these requirements.

PRIMARY CARE LICENSING

In general, primary care clinics operating in California must be licensed by the California Department of Public Health (CDPH). They must follow guidelines established by CDPH's Licensing and Certification Program (L&C) and the U.S. Centers for Medicare and Medicaid Services (see "Medi-Cal Certification" below).

There are, however, several types of clinics that are exempt from state licensure requirements. These include SBHCs run by a school district, intermittent clinics of a community health center, Tribal Clinics, and community mental health centers.

TYPES OF SCHOOL-BASED HEALTH CENTERS

SBHCs can operate under their own primary care clinic license, as a satellite or affiliate clinic of an existing medical facility, or as a mobile van.

Primary Care Clinic – If the SBHC's lead agency or medical provider is not already a licensed Primary Care Clinic (PCC), and if the SBHC and its lead agency are not otherwise exempt from clinic licensure, the site must apply for licensure through CDPH's Licensing & Certification <https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LandCProgramHome.aspx> (see "Applying for Clinic Licensure" below). SBHCs applying for PCC licensure must apply as a Community Clinic, Free Clinic, Mobile Clinic, or Rural Health Clinic. This process typically takes more than 90 business days and often the preparation takes well over a year. When an SBHC has its own primary care clinic license there is no limit to the number of hours it may provide health care services. However, this arrangement is not very common because this means that the SBHC is a standalone clinic without a "parent" clinic (see below for more information).

Intermittent or Satellite Clinic Site – An SBHC operated by a licensed PCC is exempt from licensing requirements if it is operated on a separate premises from the licensed PCC and is open no more than 40 hours a week. This is known as an intermittent clinic, sometimes referred to as a satellite site.

Federally Qualified Health Centers (FQHCs) and other medical providers frequently operate SBHCs as intermittent to a licensed, "parent" PCC. The parent PCC provides all staffing, protocols, equipment, supplies, and billing services for the intermittent site. These sites do not require separate licensure; however, they must meet all other legal requirements and administrative regulations pertaining to fire and life safety.

Affiliate Clinic – Affiliate clinics are additional sites of existing PCCs that have no restrictions on the number of hours they can operate. An SBHC can operate as an affiliate clinic if the parent clinic has held a valid, unrevoked, and unsuspended license for at least five years prior with no history of repeated or uncorrected violations of law or regulation that pose immediate jeopardy to patients as well as no pending actions to suspend or revoke a license. The process for receiving an affiliate license is significantly shorter; the law requires L&C to act on affiliate applications within 30 business days.

Mobile Health Care Unit (Van) – According to the Mobile Health Care Services Act, a "mobile service unit" can be approved as a service of a licensed clinic (similar to an affiliate clinic) or it may be separately licensed as a PCC.

More information about the requirements related to mobile health care units can be found at <https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AppPacket/PCC-Mobile-Initial.aspx>

APPLYING FOR CLINIC LICENSURE

Applications for clinic licensure are processed by the Central Application Branch (CAB) of Licensing & Certification (L&C). L&C is responsible for ensuring health care facilities comply with state laws and regulations. In addition, L&C cooperates with the Centers for Medicare & Medicaid Services (CMS) to ensure that facilities accepting Medicare and Medi-Cal payments meet federal requirements.

INTERMITTENT SITES

Notify the Department of Health Care Services (DHCS) Provider Enrollment Division (PED) of the intermittent site so that it can be added to the parent clinic's provider master file (PMF). The notification to PED should include the following:

- **FQHCs Only:** Health Resources and Services Administration (HRSA) Notice of Award: For FQHCs, the intermittent site must be added to the HRSA scope, resulting in a Notice of Award specifying the intermittent site's location. The Notice of Award must be provided to PED.
- **Memo:** Clinics must submit a letter to the DHCS PED, on corporate letterhead, requesting enrollment of the intermittent site. Guidance on the required content of the notification to PED can be found [here](#).

CAB has developed an intermittent clinic checklist that lists the documents required for establishing new intermittent sites, converting existing licensed sites to intermittent, as well as reporting changes to intermittent sites.

- **Notification to CAB:** Include the name of the "Parent" primary care clinic (include the license number, address, and contact information) and the facility operating as an intermittent clinic under the "Parent" primary care clinic (name, address, daily hours of operation, total hours per week, and contact information).
 - Once CAB receives the notification, they update and re-issue the parent license so it reflects the address of the intermittent clinic(s).

Keep a fire and safety clearance, as well as other necessary administrative regulations and requirements, on file.

Intermittent clinics must enroll directly with Medicare and receive their own Provider Transaction Access Number (PTAN). Medicare requires that the intermittent clinic be listed on the parent license prior to enrollment approval.

AFFILIATE CLINIC

When applying for a new affiliate clinic license, certain forms and fees should be submitted to the CAB prior to opening the clinic. Visit <https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/ApplyForLicensure.aspx> for more information about licensing, including all application forms and instructions.

If all the forms are complete and other conditions met (e.g., if the Parent Clinic submits evidence of compliance with the minimum construction standards of adequacy and safety), CDPH must approve an affiliate clinic license without conducting an on-site inspection.

Mobile clinics will additionally need to provide information about vehicle registration and some other items (follow previous link for mobile clinic licensing requirements).

ADDITIONAL REQUIREMENTS

For most types of primary care licenses, the following conditions must be met:

- Clear signage with clinic hours visibly posted
- Valid Certificate of Occupancy
- The health center must have a name that will be utilized for all licensing, insurance, and billing purposes
- The facility must be cleared by the fire department (see Chapter 8)

FQHCs ONLY – School-based health centers that will operate in conjunction with FQHCs but have their own independent license, should take the following steps:

- File a scope of project change with the Health Resources and Services Administration (HRSA). For FQHCs covered by the Federal Tort Claims Act (FTCA), doing so will ensure that malpractice and liability coverage includes the school-based health center. Others should contact their insurance brokers to be sure the new site is covered.
- Prepare a cost report.
- Provide a Transfer Agreement with a local hospital.

MEDI-CAL CERTIFICATION

Primary Care Clinics (PCC) that want to bill Medi-Cal must be certified. As part of the PCC licensing application, the documents below should be prepared and sent to the Central Application Branch (CAB). CAB will forward this information to the Provider Enrollment Division (PED) of the Department of Health Care Services (DHCS). PED makes the necessary updates to the provider master file (PMF) and sends the clinic a “Welcome to Medi-Cal” letter. The required certification forms are listed below and are included in the licensing application packets.

Medi-Cal Certification Forms:

- **HS 269** – Application for Medi-Cal Certification as a Clinic Provider
- **HS 328** – Notice-Effective Date of Provider Agreement
- **DHCS 9098** (8/08) – Medi-Cal Provider Agreement

Download Application Packets:

- Primary Care Clinic Application
<https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AppPacket/PCC-Initial.aspx>
- Affiliate Primary Care Clinic Application
<https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AppPacket/PCC-Affiliate-Initial.aspx>
- Template Memo for Intermittent Sites
[https://www.dropbox.com/s/i86dbbcud6ze0gw/Intermittent Site Medi-Cal Enrollment.pdf?dl=0](https://www.dropbox.com/s/i86dbbcud6ze0gw/Intermittent%20Site%20Medi-Cal%20Enrollment.pdf?dl=0)

Note: Intermittent clinics are not required to have a separate Medi-Cal provider number; however, the state recommends that the parent clinic notify the Medi-Cal PED when opening an intermittent site. You can use the template memo above to notify PED.

OSHA

School-based health centers should comply with the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) rules, and staff should receive yearly training on OSHA rules and requirements. This typically includes, at a minimum, having plans for blood borne pathogen exposure, and planning for infectious and biohazardous waste management. Staff should always practice universal precautions. For further information on OSHA see www.osha.gov.

LABORATORY REQUIREMENTS

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires all entities that perform even one laboratory test to meet certain federal requirements and register with the CLIA program. To apply for CLIA certification, you must fill out the CLIA Application for Certification, Form CMS-116, from The Centers for Medicare and Medicaid Services, and mail it to the California Department of Public Health. The CLIA application collects information about a laboratory's operation, which is necessary to determine the type of certificate to be issued and relevant fees. All CLIA certificates are effective for two years. An overview of this process, and information on the different types of CLIA certificates, is provided in the document, "How to Obtain a CLIA Certificate" (www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf).

INSURANCE PROGRAM CERTIFICATION

CHILD HEALTH AND DISABILITY PROGRAM

The Child Health and Disability Prevention (CHDP) Program is a partial insurance program that reimburses providers for providing periodic health assessments and other preventive health care services to low-income children and youth.

Preventive care services include comprehensive physical exams and mandated screenings such as dental, vision, hearing, and specified laboratory tests. The CHDP program also provides care coordination to assist families with medical appointment scheduling, transportation, and access to diagnostic and treatment services.

CHDP services can be provided by private physicians, nurse practitioners, local health departments, community clinics, and school districts. Clinics can participate in the CHDP program as a "comprehensive care" or "health assessment only" provider. Comprehensive care providers deliver not only health assessment services but also serve as the primary care home for the patient, inclusive of all treatment, follow-up, and medical case management.

To become a CHDP provider and be reimbursed for services provided under this program, the agency providing medical services must complete the CHDP Health Assessment Provider Application. Medical providers may apply to become a CHDP provider simultaneously with the primary care clinic licensing application. For more instructions on how to apply: www.dhcs.ca.gov/services/chdp/Pages/BecomingaCHDPPProvider.aspx.

Once an application is received, the local CHDP program (usually operated by the County or other local health department) performs an on-site review of an applicant's site to assure that a minimum standard is maintained in the delivery of quality care. The review includes a facility review and medical record review.

FACILITY REVIEW – All CHDP provider service sites must receive an initial on-site review; these sites may also have subsequent periodic inspections. A facility review is conducted to assess site access and safety, including the presence of appropriate emergency medical equipment and supplies; personnel qualifications, licensure and/or certification; site management; and compliance with CLIA. Specific components of the facility review tool are defined as "critical elements" which must be in full compliance before the facility can be considered for approval. Critical elements include the following:

- Appropriate equipment and staff training for airway, breathing, and circulatory management
- Emergency medication on-site for anaphylactic reactions to immunizations
- Current professional licenses for site and all medical providers
- Participation in the Vaccines for Children program
- Compliance with the Pharmaceutical Services Survey Criteria
- Compliance with the Preventive Services Survey Criteria

MEDICAL RECORD REVIEW – The medical record review is performed to ensure that CHDP clients receive appropriate levels of care. Reviewers check for the following:

- **Format:** A well-organized system that permits confidential client care and quality review.
- **Documentation:** Well-documented medical records that facilitate communication and coordination, and promote the efficiency and effectiveness of treatment.
- **Coordination and Continuity of Care:** The medical record includes the client’s past and current health status, medical treatment, and future health care plans to ensure seamless continuity of care for the child.

More information on the CHDP application and review process can be found at <https://www.dhcs.ca.gov/services/chdp/Pages/default.aspx> and in the CHDP Provider Manual at https://files.medi-cal.ca.gov/pubsdoco/chdp_manual.aspx

FAMILY PACT

Family PACT (Planning, Access, Care, and Treatment) is a state-run program designed to ensure access to reproductive health care services for uninsured and under-insured California residents. Services covered include reproductive health education, gynecological and male health exams, birth control methods, pregnancy testing, and testing and treatment for sexually-transmitted infections. Services can be provided by both licensed medical staff as well as unlicensed health educators. For more information, see <https://familypact.org/>

SBHCs can be reimbursed for providing these services to eligible clients by enrolling as a Family PACT provider. To become a Family PACT provider, the agency must be licensed as a primary care clinic and Medi-Cal provider in good standing; attend a provider orientation session; and submit completed Application and Enrollment Agreement forms. Certain services must be in place, as well as referral resources, and assurances of client confidentiality. For more details and to access these forms, visit <https://familypact.org/providers/enrollment/>.

TITLE X

In 1970, Title X of the Public Health Service Act established the nation’s Population Research and Voluntary Family Planning Programs. Title X is a federal grant program designed to provide comprehensive family planning services, including contraceptive supplies and information, to low-income individuals.

The Title X Family Planning program is administered by the U.S. Office of Family Planning (OFP). Title X grantees include community health centers, public health departments, tribal organizations, hospitals, and university health centers. In addition to contraceptive services and counseling, Title X clinics provide preventive health services such as breast and pelvic examinations; breast and cervical cancer screening; STI and HIV testing; and pregnancy testing and counseling.

Although the funding that programs receive from Title X does not begin to cover all the costs incurred in providing this care, it can help to subsidize the revenue received from Family PACT. In addition, Essential Access Health (EAH) – the organization that distributes Title X funds in California – also provides agencies with a variety of technical assistance and training, and raises money from private foundations and research grants which it passes on to delegates. In recent years, EAH has operated several grant programs focused on adolescents and SBHCs directly. In return, participation in Title X requires that health centers follow certain federal guidelines and collect specified data on clients, their birth control methods, and services provided.

To learn more about how to become a Title X agency, consult the OPA grants page at <http://www.hhs.gov/opa/grants/index.html>. Requests for proposals are released periodically.

VACCINES FOR CHILDREN PROGRAM

The Vaccines for Children (VFC) Program, established by an act of Congress in 1993, helps families by providing free vaccines to doctors who serve eligible children 0 through 18 years of age. In California, the VFC Program is administered by the California Department of Public Health (CDPH) Immunization Branch. Through this program, the state contracts with vaccine manufacturers to buy vaccines at reduced rates. Enrolled VFC providers then order vaccines for eligible children through the VFC Program and receive routine vaccines at no cost. To be eligible, children must be 18 years of age or younger and eligible for Medi-Cal or CHDP, uninsured, or American Indian or Alaskan Native. Children enrolled in the Healthy Families program are not VFC-eligible. Children who have health insurance that does not cover immunizations may receive VFC vaccines, but only at federally qualified health centers or rural health clinics.

Any California-licensed physician or health care organization serving VFC-eligible children can become a VFC provider. Once certified, VFC providers must record patients' eligibility status and comply with CDC's Standards for Pediatric Immunization Practices (<https://www.cdc.gov/mmwr/preview/mmwrhtml/00020935.htm>). Providers are visited periodically by a VFC Field Representative who conducts a Quality Assurance Review.

MENTAL HEALTH PROGRAMS

The California Department of Mental Health administers behavioral health programs for children and youth. It is beyond the scope of this manual to fully outline all the mental health programs in California. In terms of mental health *insurance program certification*, the most important is the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program. This is a billable program for children and youth under 21 years old who qualify for full-scope Medi-Cal and need therapeutic behavioral health services. EPSDT providers may be employed by a county, a community mental health agency, or a school district. EPSDT is managed by county mental health/behavioral health departments. To become an EPSDT provider, you must establish a contract with your local county behavioral health department; please contact them for details.