



This letter is to assist the clinic corporation (licensee) in preparing an primary care clinic (PCC) - affiliate licensing and/or certification (for Medi-Cal Title 19 reimbursement) application package to the California Department of Public Health (CDPH), Licensing and Certification (L&C) Program for:

- ➤ Initial "Affiliate" primary care clinic (PCC) licensing application package for a community or free PCC, including mobile health care units; or
- Change of ownership (CHOW) primary care clinic affiliate licensing application package for a community or free PCC, including mobile health care units.

A state license is required to operate a "community" or "free" PCC in California, which are defined as:

Community clinic means "a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding scale," pursuant to Section 1204 (a)(1)(A) of the Health and Safety (H&S) Code.

Free clinic means "a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished," pursuant to Section 1204 (a)(1)(B) of the H&S Code.

An application is required for:

- 1. A new (initial) PCC affiliate.
- 2. A CHOW, within 10 working days whenever a CHOW occurs. A CHOW is the only "change" requiring a new application package to be submitted to L&C's Centralized Applications Unit (CAU), pursuant to Section 75021 of Title 22 of the California Code of Regulations (CCR). The PCC will have to meet the affiliate criteria (explained below) to apply for a CHOW.

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Conditions for an PCC- affiliate license.

The affiliate clinic must meet the following conditions pursuant to Section 1218.1 of the Health and Safety (H&S) Code:

- 1. A clinic corporation, on behalf of a currently licensed PCC, is eligible to apply for an affiliate clinic license to establish a new PCC at an additional site or a mobile clinic [affiliate clinic(s)] provided the licensed PCC has:
 - Held a valid, unrevoked, and unsuspended license for at least five
 (5) years immediately prior to the date of application with no history of repeated or uncorrected serious violations affecting patient safety, constituting "immediate jeopardy," and
 - No pending action to suspend or revoke its license.
- 2. The parent and affiliate clinics' corporate officers, as specified in Corporations Code, Section 5213, are the same.
- 3. The parent and affiliate clinics are owned and operated by the same nonprofit organization with the same board of directors.
- 4. The parent and affiliate clinics have the same medical director or directors and medical policies, procedures, protocols and standards.

Application package for "changes" to an PCC – affiliate – besides a CHOW. "Changes", not a CHOW, (change agency name; mailing address; location; administrator; director of patient care services; directors and board members; etc.) must be requested by submitting the appropriate forms to the L&C CAU.

These "changes" (not a CHOW) do not require submittal of an entirely "new" application package. CAU will assist you on which forms that must be submitted for the specific change to the license.

Required Forms.

Please review the required forms to license and certify a PCC which are posted on the L&C website:

https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/HealthFacility-PCC.aspx

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Exempt PCCs wishing to enroll in the Medi-Cal Program need to contact the Department's Provider Enrollment Division for their Medi-Cal application package at the Department of Health Care Services website:

http://medi-cal.ca.gov

Dental Clinics.

Applicants wishing to enroll in the Denti-Cal Program must also contact the Department of Health Care Services, California Medi-Cal Dental Program, at 1-800-423-0507 or at the Department of Health Care Services website:

http://www.denti-cal.ca.gov

Federally Qualified Health Centers (FQHC).

FQHC and FQHC Look-Alikes should submit Medi-Cal certification forms along with the licensing application forms directly to CAU.

FQHC is a reimbursement designation from the Centers for Medicare & Medicaid Services. The main purpose of the FQHC Program is to enhance the provision of primary care services in underserved urban and rural communities. FQHCs include all organizations receiving grants under Section 330 of the Public Health Service Act. FQHCs qualify for enhanced reimbursement from Medicare & Medicaid as well as other benefits. FQHCs must serve an underserved area or population, offer a sliding fee scale, provide comprehensive services, have an ongoing quality assurance program, and have a governing board of directors.

Checklist.

For your convenience, the attached checklist has instructions to complete the forms required for licensing and certification of a PCC. The checklist provides specific item numbers that applicants typically have encountered problems in submitting incorrect or missing information. Please make sure that all item numbers in each form are completely filled out. For example: (1) the applicant's formal name must be consistently the same throughout all the documents in the application package; or (2) in some instances, a specific attachment may need to be submitted with a specific form. All forms are required to be signed by the "licensee", owners or officers, unless otherwise stated.

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Application Package.

Please read each required application package form carefully and provide all requested supplemental documents. Do not leave any items blank. **Note:** If a question does not apply, please respond with "Not Applicable" or "N.A." Do not make changes to these forms. Use "blue" ink to sign all forms. Do not use white out/correction fluid to make corrections. To correct an error, place a single line through the entry and enter the correct information. The individual responsible for making the correction must initial and date the correction. You should retain a photocopy of the completed documents for your files. We may need to contact you in the future and we will be referring to the information in the documents you provided.

Submission of Affiliate PCC Applications.

All completed Affiliate PCC application packages must be submitted to the L&C CAU address (regular mail), listed below:

California Department of Public Health Licensing and Certification Program Centralized Applications Unit P.O. Box 997377, MS 3207 Sacramento, CA 95899-7377

The CAU will review the application package for completion. Once the application package has been approved by the CAU and all required surveys have been performed the CAU will issue the license accordingly.

Fee.

In addition, a check or money order, made payable to the "California Department of Public Health", for the licensing fee, determined pursuant to Section 1266 of the H&S Code, must accompany the required forms before your application will be processed. The licensing fees change annually; therefore please check the current licensing fee for a PCC-Affiliate which is posted on the L&C Facility Fee website:

https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LC-Health-Care-Facility-Licensing-Fees.aspx

The application fee will not be returned if the application package is withdrawn or denied, pursuant to Section 75023 of Title 22 of the California Code of Regulation.

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Affiliate PCC Approval Process.

- 1. The forms, documents, and information necessary to complete an affiliate clinic application are noted on the checklist.
- 2. If the applicant meets all conditions of licensure for an affiliate clinic, CAU, will issue a license within 30 days of receipt of a completed application. If CAU approves a completed application sooner, the CAU will issue a license within seven (7) days of such approval.
- 3. If CAU determines that the applicant does not meet the conditions of licensure for an affiliate clinic, CAU will provide in writing to the parent clinic the reasons for that determination and for not approving the application within the 30-day period. CAU will instead process the application under H&S Code Section 1218.
- 4. District offices (DO) may, at their discretion, conduct a licensing survey under H&S Code, Section 1278, at any time after the receipt of the completed application. However, CAU cannot delay issuance of the license pending a survey.

Review Process.

The application package review process will consider the applicant's and associates' (i.e., board members, LLC members, managers, etc.) past compliance history. This will be based on a review of all facilities and agencies operated by those individuals in California and nationally. The applicant and associates must demonstrate substantial compliance with state and federal requirements for all facilities that they operate.

Failure to demonstrate substantial compliance history may result in the denial of your application package. You will be notified in writing of L&C's intent to deny the application.

National Provider Identifier.

To apply for National Provider Identifier (NPI), go to the National Plan and Provider Enumeration System website:

https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instruction

The NPI number is not required for a "licensed" only facility.

If you have any questions, please contact the CAU, at (916) 552-8632 or by e-mail at CAU@cdph.ca.gov.

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Applicant Checklist

The following is a quick reference of <u>some</u> of the questions found on the required forms. It includes the form number, name of form, and an explanation of specific requirements and/or attachments needed for specific forms. This is <u>not</u> an all-inclusive list of the questions that need to be answered so read the questions and instructions on each form.

<u>Licensure</u>

Form #	Item #	Description	Check List
Affiliate Clinic		Affiliate Clinic Criteria [H&S Code, Section 1218.1)]	
Criteria		 Note: A clinic corporation, on behalf of a currently licensed PCC, is eligible to apply for an Affiliate clinic license to establish a new PCC at an additional site or a mobile affiliate clinic provided that the following can be verified: The "licensed" parent PCC has held a valid, unrevoked, and unsuspended license for at least five years immediately prior to the date of application with no history of repeated or uncorrected serious violations affecting patient safety, constituting "immediate jeopardy". The parent PCC has no pending action to suspend or revoke its license. The parent & Affiliate PCCs' are both owned and operated by the same non-profit organization. Submit an organization chart. The parent & Affiliate PCCs' corporate officers are both the same. Include this information on the organization chart requested under #3 (above). The parent & Affiliate PCCs' board of directors & board members are both the same. Include this information on the organization chart requested under #3 (above). 	

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Form #	Item #	Description	Check List
CDPH		Licensure & Certification Application For An Affiliate PCC	
611		Note: Please read the instructions on the CDPH 611 form.	
		(H&S Code Section 1218.1)	
	A.	Application Information	
		Submit Fee	
		Identify type of affiliate clinic	
	B.	Clinic Corporation (Licensee) Information.	
		Complete question as required.	
	C.	Parent Clinic Information.	
		Complete question as required	
	D.	Affiliate Clinic Information.	
		Complete question as required.	
	E.	Mobile Clinics.	
		Complete question as required.	
	F.	Property Information.	
		Submit copy of Grant Deed, Bill of Sale, Lease, Purchase	
		Agreement, Sublease, Rental Agreement, or	
		memorandum of understanding between the owner of	
		the property and the proposed licensee.	
		[H&S Code Section 1218.1(b)(10)]	
		Note: N/A for Mobile	
	Sign	Signature.	
		"Original signature is required and must be signed by the applicant. Owners must sign if the applicant is "for-profit". Office and making if the applicant is "for-profit".	
		Officers may sign if the applicant is "non-profit".	

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Form #	Item #	Description	Check List
Title 24	#	Title 24 Building Code Compliance [H&S Code, Sections 1218.1 & 1226.3)] Note: If this is not a previously licensed clinic, submit the Title 24 requirements listed under number 1 below. This is N/A for mobile clinics. [H&S Code, Sections 1217 and 1226.3] Submit the following documents if this is a newly constructed and/or remodeled building. N/A for CHOWS, unless there has been construction and/or remodeling. 1. Written certification of Title 24 compliance from a California licensed architect or local building authority. The written statement must state that the building meets the following:	List
		were alterations or repairs to existing buildings performed or conversion of space).	

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Form #	Item #	Description	Check List
	#	Applicant Individual Information [Title 22, Continue 75002	LIST
HS		Applicant Individual Information [Title 22, Sections 75022	
215A		and 75025 and H&S Code, Sections 1212 and 1218.1)]	
		Note: Please read the instructions on this form prior to completion of the form.	
		 Submit the following documents for the following individuals with original signatures. 	
		Administrator.	
		 Governing Body signed written statement for Administrator. [Title 22, Section 75045(d)] 	
		2. Administrator's Job Description approved by	
		governing body. [Title 22, Section 75022]	
		3. HS 215A form for Administrator.	
		4. Resume for Administrator.	
		[Title 22, Section 75022(a)(4)]	
		5. The Administrator may be responsible for more than	
		one clinic only if all clinics are operated by the same	
		Governing Body. The Administrator shall include the	
		name & number of hours spent in each facility they	
		are employed, per week.	
		[Title 22, Sections 75022(a)(4) & 75046(c)]	
		Administrator's Designee.	
		 Administrator shall designate, in writing, the 	
		appointment of the Administrator's Designee.	
		[Title 22, Section 75046(d)]	
		HS 215A form for Administrator's Designee.	
		Resume for Administrator's Designee.	
		[Title 22, Section 75046(b)]	
		Applicant Organization.	
		HS 215A form is required only if there are new	
		directors, board members, corporate officers, LLC	
		members/managers, and partners of the applicant	
		organization. Note: Since PCC's are non-profit, there	
		is no facility ownership.	

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Form #	Item #	Description	Check List
HS 215A (cont.)		Parent Company. 1. HS 215A form is required only if there are new individuals of the parent, grandparent, great grandparent, organization. Note: Since PCC's are non-profit, there is no facility ownership. 2. HS 215A form is only required if there are new of directors, board members, corporate officers, LLC members/managers, and partners of the parent, grandparent, great grandparent organization.	
	D.	 Management Company. Employment/Business Summary (for last 10 years). A resume or attachment will be acceptable in lieu of Section "D" being filled out. 	
	E.	Facility, Agency, Clinic Involvement (in or out of California).	
	Fac Info Sheet	Facility Information Sheet [H&S Code, Section 1218.1] Note: If you answer "Yes" in Section E above (Facility, Agency, Clinic Involvement) you must complete the Facility Information Sheet for each HS 215A form submitted (except for the Administrator, unless they are the owner). Each individual must complete the "Facility Information Sheet" for each facility and/or agency with which they have a current or past relationship within the last 3 years which must include facilities licensed by CA Department of Social Services. An attachment may be submitted in lieu of the Facility Information Sheet, if all applicable information is on the attachment.	
		The following must be completed for each facility and/or agency: • Facility name and address • Type of facility • Type of business entity and EIN number • Person's nature and dates of involvement • This Sheet must also include any facilities licensed by the California Department of Social Services.	
	Sign	Signature. [H&S Code, Section 1218.1]Original signature is required on all of the HS 215A forms.	

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Form	Item	Description	Check
#	#		List
STD		Fire Safety Inspection Request	
850		 This form is required for "initial" applications. 	
		 This form is not required for a change of ownership. 	
		The STD 850 form must be submitted or a similar form	
		from the fire authority. If the STD 850 form is not	
		submitted, the fire authority form will need to contain	
		equivalent information as the STD 850 form.	
		If the fire authority refuses to accept the STD 850 form	
		from the applicant, CAU will send the form on behalf	
		of the applicant.	
		Mobile PCC:	
		The STD 850 form would always be required for mobile	
		units that require utility hookups with a general acute care	
		hospital. This could be a trailer, i.e., mobile home, without	
		wheels. Normally this never applies to PCC mobile clinics.	
		[H&S Code, Sections 1765.150(b) & 1765.155(a)]	
DHCS		Civil Rights Compliance Review	
1051			
		Send directly to Office of Civil Rights – address is on last	
		page of the form.	

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Form #	Item #	Description	Check List
		Mobile Clinic In addition to all of the above forms, Mobile PCC must submit the following documents: 1. DMV: Vehicle registration, including ID, type and manufacturer. [H&S Code, Section 1765.120(a)] 2. Inspection Approval: Department of Housing & Community Development (HCD) "Inspection Approval" copy of the HCD's "insignia". [H&S Code, Section 1765.120(b)] 3. Self-Contained: OSHPD approval (if not self-contained) or letter from provider verifying that unit is self-contained. [H&S Code, Sections 1765.150(b) and 1765.155(a)] 4. Not Self Contained: If a mobile unit is not self-contained, OSHPD approval is only required if the utility hookups originate or pass through any GACH building. According to OSHPD, it would be rare that a mobile clinic would connect to an GACH facility. 5. Local Planning/Zoning Approval: [H&S Code, Sections 1765.150(e) & 1765.155]	
		The licensed parent facility or clinic shall be responsible for obtaining approvals for the site or sites of the mobile unit as required by the local planning, zoning, and fire authorities.	
CHOW		 Change of Ownership Submit all of the forms required for an "initial" application, listed above, plus the following: Copy of "Purchase Agreement" or "Operating Transfer Agreement". A letter from the prospective licensee to CDPH stating where the stored patient medical records will be maintained, and that the records will be made available to the previous licensee. [Title 22, Sections 75021(3) & 75055(e)] 	

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<u>Medi-Cal Certification</u> PCC-Affiliate - Including Mobile Clinics

Form #	Item #	Description	Check List
HS 269		 Application for Medi-Cal Certification as a Primary Clinic Provider. Form requires a National Provider Identifier number in lieu of the Medi-Cal provider number. 	
HS 328		Notice – Effective Date of Provider Agreement Submit this form.	
DHCS 9098		 Medi-Cal Provider Agreement [US Code, Title 42, Section 1396a(a)(27); and CFR, Title 42, Part 431.107; and W&I Code, Section 14043.2; and Title 22, Section 51000.30(a)(2)] 1. Do not leave any questions blank. Must enter N/A or "same", if not applicable. 2. The "mailing address" must be the same as reported on the CDPH 611 form, Section "D". 3. Signature page (page 9) must contain original signatures. (CA Civil Code, Title 4, Section 1189) 4. Submit the "Acknowledgement" page from the Notary Public, if applicable. Note: Applicant must request the "Acknowledgement" page from the Notary Public. 	

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