



APPLICATION REQUEST FOR A PRIMARY CARE CLINIC or



PRIMARY CARE CLINIC WITH RURAL HEALTH DESIGNATION

This letter is to assist you in preparing a primary care clinic (PCC) licensing and/or certification (for Medi-Cal Title 19 and/or Medicare Title 18 reimbursement, for a PCC with **Rural Health** designation) application package to the California Department of Public Health (CDPH), Licensing and Certification (L&C) Program for:

- Initial application package licensing of a “community” or “free” PCC; or
- Initial application for a PCC designated as a Rural Health Clinic (RHC); or
- Change of ownership (CHOW) application package for a “community” or “free” PCC and RHC.

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 package is required for: (1) a new (initial) PCC and (2) 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). All other changes (besides a CHOW) must also be reported to the L&C District Office (DO) in writing within **10 days** of the change, pursuant to Section 75025 of Title 22 of the CCR. These other changes do not require submittal of a new application package. The DO will assist you on which forms on the checklist that must be submitted for the specific change to the license.



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For your convenience, the [attached checklist](#) has instructions to complete the forms required for licensing; and/or licensing and Medi-Cal enrollment; and/or certification of the following:

- PCC LICENSURE
- PCC ENROLLMENT in Medi-Cal
- CERTIFICATION of a RHC for Medicare (PCC with RHC designation)
- **EXEMPTION** from LICENSURE; but applying for a RHC designation and to enroll in the Medi-Cal Program.

NOTE: CAU does **NOT** process application packages for EXEMPT PCCs (**EXEMPT from licensure**). A clinic exemption list can be found at:

<http://www.cdph.ca.gov/pubsforms/forms/Pages/HealthFacilities-Clinics.aspx>

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 their Branch website at:

<http://medi-cal.ca.gov>

The [checklist](#) provides specific item numbers that applicants typically have encountered problems in submitting incorrect or missing information. Please make sure that all the 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.

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.** 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 corrections. You should retain a photocopy of the completed documents for your files.

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 package will be processed. The licensing fees change annually; therefore please check the current application fee for a PCC which is posted on the L&C website at:



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<http://www.cdph.ca.gov/pubsforms/forms/Pages/HealthFacilities.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 CCR.

The application package review process will consider the licensee's and board members' prior compliance history of all facilities 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 historically may result in the denial of your application package. You will be notified in writing of L&C's intent to deny the application.

All completed PCC **application packages must be submitted to the L&C CAU address** (regular **or** overnight mail), listed below. Please note that "overnight" mail may actually take longer for the CAU to receive because of our CDPH in-house mail services.

For overnight (FedEx-UPS):

California Department of Public Health
Licensing and Certification Program
Centralized Applications Unit
1615 Capitol Avenue, MS 3402
Sacramento, CA 95814

For regular mail:

California Department of Public Health
Licensing and Certification Program
Centralized Applications Unit
P.O. Box 997377, MS 3402
Sacramento, CA 95899-7377

The CAU will review the application package for completion and forward it to the appropriate district office once the application package has been given a recommendation of "approved". A list of district offices and appropriate contacts are located on the L&C website mentioned on the previous page.

Please NOTE the following:

1. There are some differences between documents required for a CHOW, and "initial" application packages that are noted on the [checklist](#).
2. An initial survey is part of the application process for "new" PCC facility applications.
3. The initial survey is a scheduled survey conducted by L&C district offices in the facility.



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4. If your clinic wishes to be certified as a **RHC** and will provide services to **Medicare beneficiaries** (under Title 18) or **Medi-Cal beneficiaries** (under Title 19) you will need an additional **certification survey** that is unannounced and will be conducted by one of the L&C district offices. The survey will determine if you are in compliance with the federal requirements for a RHC. This survey will be in addition to the initial licensing survey you had if you are a new clinic.
5. Once you have had your initial licensing survey, you must notify the L&C district office that you are ready and prepared to have an initial certification survey.
6. In addition, you must be in compliance with state licensing laws and federal conditions of participation.

NOTE: Affiliate Clinics

1. A primary care clinic that has held a valid, unrevoked, and unsuspended license for at least **five (5) years** prior with no history of repeated or uncorrected violations and no pending actions to suspend or revoke a license, may apply to establish a new PCC at an additional site. These additional sites are called “affiliate clinics.”
2. Once the application is deemed complete, CAU has **30 days** to review and approve the application. Once the application is approved, CAU will send the application to the district office. District offices must issue a regular license to the affiliate clinic upon receipt of the approved application from CAU within **seven (7) days**. The conditions for this to occur are noted on the [checklist](#).
3. If the application is deemed not to meet the conditions as stated above, CAU must submit in writing to the parent clinic the reasons why L&C is not approving the application within the **30-day** period.
4. There is nothing to prevent district offices from conducting a licensing inspection at any time after the receipt of the completed application. However, district offices cannot delay issuance of the license until an inspection has taken place. The regular license must be issued within **7 days** of receipt of the application packet by the district office.

NOTE: Rural Health Clinics

Prior to submitting an application package, submit the CMS 29 and HS 610 to CAU to determine whether or not the location qualifies based on the census tract number. As you are aware in order to be certified, the rural health clinic must be located in an area that is not an urbanized area and in a medically underserved area (MUA) or health profession shortage (HPS) area. CMS will determine if the location qualifies and the Office of Statewide Health Planning and Development (OSHPD) will determine if it's in a HPS or MUA area. Once CAU is notified of the determination CAU will notify you whether or not to submit an application package.



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The district office will notify you when the application has been approved and will schedule an initial licensing survey. NOTE: YOU MUST BE READY FOR THE INITIAL LICENSING SURVEY UPON NOTIFICATION. It is L&C's policy that, except in unusual circumstances, only one inspection visit will be made. Failure of the facility to be in substantial compliance, at the time of the visit, will result in the "denial" of the application package. Any further activity regarding your request, after such denial, will require a new application and license fee.

PLEASE NOTE: A license will not be issued until both the application is approved and, if required, a successful licensing survey is conducted.

If you have any questions, please contact the Centralized Applications Unit, at (916) 552-8630 or by e-mail at CAU@cdph.ca.gov.

Sincerely,

ORIGINAL to be SIGNED BY:

Anna Ramirez, Chief
Field Operations Branch—Region IV



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Form Number	Item Number on Form	<h2 style="text-align: center;">PROVIDER CHECKLIST</h2> <p style="text-align: center;">for PRIMARY CARE CLINICS</p> <p>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 <u>SPECIFIC</u> requirements and/or attachments needed for specific forms. This is NOT an all-inclusive list of the questions that need to be answered so read the questions and instructions on each form.</p>	Check List
<h3>LICENSURE</h3> <h4>PRIMARY CARE CLINICS</h4> <p>Includes the forms and information required to be "licensed". All Primary Care Clinics MUST be licensed unless they are EXEMPT from licensure.</p>			
HS 200	Licensure & Certification Application (Title 22, Section 75021) NOTE: Please read the instructions on the HS 200 form prior to completion of the form. Also, pay close attention to the following items:		
	A.4.c.	Change of Location. Complete the CDPH 414 form . Also, refer to the requirements under Item A.11. (Construction).	
	A.11.	Construction. (Title 22, Section 75060) SUBMIT the following documents for "initial" applications. N/A for CHOWS, unless there has been construction and/or remodeling. If this is a newly constructed and/or remodeled building, SUBMIT the following: <ul style="list-style-type: none"> • Written certification of Title 24 compliance from a California licensed architect or a local building authority • Certificate of Occupancy If this is NOT a previously licensed facility, or if it is an "affiliate" clinic, SUBMIT the following: (H&S Code, Sections 1217 and 1226.3) Written certification of Title 24 compliance from a California licensed architect or local building authority. This is not required for a change of ownership. The written statement must state that the building meets the following: <ul style="list-style-type: none"> • California Building Code • California Electrical Code • California Mechanical Code • California Plumbing Code <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • The California licensed architect or local building authority may use the attached form, "Certification Form for Clinics and Freestanding Outpatient Clinic Services of a Hospital". 	
	B.1.	Licensee's name. [Title 22, Section 75022(a)(3)] The licensee's formal organization name must be consistent throughout all documents.	



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	B.3.	Owner type. SUBMIT an organization chart/flow chart if the owner is a profit or nonprofit corporation, limited liability company (LLC), or general partnership. The organization chart needs to display the following: <ul style="list-style-type: none"> • Applicant's owners/officers and board/LLC members • All agencies/facilities the applicant is involved with • Management company of applicant, if applicable, and all of their facilities • Parent company of applicant, if applicable, & all their agencies/facilities – See B.6. If nonprofit, SUBMIT a copy of Internal Revenue Service letter of determination status acknowledging tax-exempt nonprofit corporation. [H&S 1204 (a)(1)(A)(B)]	
	B.5.a.	Licensee's "other" Facility Involvement. Answer all aspects of the question.	
	B.5.b.	Revocation, suspension, etc. action. If applicable to the licensee, SUBMIT the information requested.	
	B.6.	Subsidiary information. If there is a "subsidiary" (parent company) SUBMIT : <ul style="list-style-type: none"> • An organization chart with the parent company name and tax ID number • A listing of all owners/officers of the parent company • A listing of all facilities the parent company is involved with 	
	C.1.a.	Management Company. This question does not apply to primary care clinics.	N/A
	C.1.b.	"Interim" Management Company Agreement. NOTE if Change of Ownership: If there is an "interim" Management Company Agreement, between the current and the prospective licensee, SUBMIT a signed and dated copy of Agreement.	
	C.2.	Name of "proposed" and "current" facility. Enter both facility names if this is a CHOW.	
	C.6.a.	Administrator. [Title 22, Sections 75022(a)(4), 75025(b) and 75046] SUBMIT the HS 215A form for the Administrator of the facility.	
	C.6.b.	Director of Nursing.	N/A
	C.7.	Ownership. <ul style="list-style-type: none"> • List all persons having 5% or more ownership, unless "nonprofit". • SUBMIT the HS 215A form for each of these persons. 	
	C.8.	Financial resources. This question only applies to skilled nursing facilities and intermediate care facilities, per the HS 200 form instructions.	N/A



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	C.9. & C.10.	Over-concentration and Program Plan. These questions are "N/A" for PPCs.	N/A
	D.1. & D.2.	Property ownership. SUBMIT a copy of the Grant Deed, Bill of Sale, Lease, Sublease, or Rental Agreement between the owner of the property and the proposed licensee. NOTE: This is not applicable for mobile clinics.	
	F.1.	Signature. "Original" signature is required and MUST be signed by the LICENSEE (not the Administrator).	
	Attach E-1	Management Company Information. Attachment E-1 does not apply to primary care clinics.	N/A
HS 215A	Applicant Individual Information (Title 22, Sections 75022 and 75025) NOTE: Please read the instructions on the HS 215A form prior to completion of the form. This form must be completed for the following persons with ORIGINAL signatures:		
		<ul style="list-style-type: none"> • Administrator of the facility – Administrator shall include the name and number of hours spent in each facility they are employed, per week. [Title 22, Section 75022(a)(4)] • Board members, directors, partners, and corporate officers of the applicant organization and parent organization • Each person having a beneficial interest of 5% or more in the applicant organization and parent organization (only applies for a PCC with rural health designation) • LLC managers and members • Partners 	
	Signature	Signature. Original "signature" is required.	
	Facility Info. Sheet	Facility Information Sheet. Each individual must complete and SUBMIT the "Facility Information Sheet" for each facility with which they have a <u>current</u> or <u>past</u> relationship (going back 3 years). The following <u>MUST</u> be completed for each facility: <ul style="list-style-type: none"> • Facility name • Address of facility • Type of facility • Type of business entity • Person's <u>nature</u> of involvement • Person's dates of involvement • This Sheet must also include any facilities licensed by the California Department of Social Services. 	



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HS 309 1 st page	Administrative Organization [Title 22, Section 75022(a)(2)]		
	2.	Administrator of Corporation or LLC – This is usually the CEO/President.	
	3. thru 7.	Corporations need to SUBMIT : <ul style="list-style-type: none"> • A copy of the Filing Statement from Secretary of State • Copy of all Articles of Incorporation • Copy of By-Laws 	
	9.	Governing Board of Directors. SUBMIT a list of board of directors SUBMIT the HS 215A form for each person listed under this item	
	10.	Board Officers. SUBMIT the HS 215A form for each person listed under this item	
HS 309 2 nd page	Organizational Structure [Title 22, Section 75022(a)(2)]		
	1.	California Out-of-State Corporations, LLC, etc. SUBMIT a copy of the Certificate of Qualification from the California Secretary of State	
	3. thru 4.	Public Agency. SUBMIT a copy of the Resolution	
	5.	Item 5. Corporations and Partnerships need to complete Item 5	
	Bottom of page	Partnerships need to SUBMIT : <ul style="list-style-type: none"> • A copy of the Partnership Agreement • Copy of the California Secretary of State filing • HS 215A form for every person listed under this item 	
	Bottom of page	Limited Liability Companies (LLC) will need to SUBMIT : <ul style="list-style-type: none"> • Copy of Filing Statement from the Secretary of State • Copy of Articles of Organization • Copy of Operating Agreement • List of Members / Holders / Officers / Managers – SUBMIT the HS 215A form for each person listed under this item 	
HS 602	Transfer Agreement Between (Title 22, Section 75047)		
		The Transfer Agreement needs to be current. Please SUBMIT a copy of the Transfer Agreement.	
HS 609	Bed or Service Request		
	Top of page	Under “Requested Beds” category, the “Approved Capacity” should be left blank.	
	Bottom of page	Check the “clinic only” on the bottom right-hand portion of this form.	



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STD 850	Fire Safety Inspection Request (Title 22, Section 75061)	This is only required for "initial" applications. It is NOT required for a change of ownership or for "mobile clinics". If the fire authority refuses to accept the STD 850 from the applicant, CAU or the district offices will send the STD 850 on behalf of the applicant.	
DHCS 1051	Civil Rights Compliance Review	Send directly to Office of Civil Rights – address is on last page of the form.	
None	Change of Ownership [Title 22, Section 75021(3)]	SUBMIT all of the forms required for an "initial" application, listed above, plus 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, Section 75055(e)]	
None	MOBILE CLINIC (H&S Code, Sections 1765.120, 1765.150 & 1765.155) <u>Note:</u> In addition to the above forms, mobile PCC must SUBMIT the following forms:	<ul style="list-style-type: none"> • Vehicle registration, including ID, type and manufacturer. • Department of Housing Inspection Approval. • OSHPD Approval (if NOT self-contained) or letter from provider verifying that unit is self-contained. • Local Planning/Zoning approval 	
None	AFFILIATE CLINIC (H&S Code, Section 1218.1) <u>Note:</u> In addition, the parent clinic needs to SUBMIT <u>in writing</u> the following. See page 4 of this letter for further explanation.	<ul style="list-style-type: none"> • The parent clinic submitted completed application and fee for licensure for affiliate. • The parent clinic (must be identified in statement) and affiliate clinic corporate officers are both the same. • The parent clinic and affiliate clinic are both operated and owned by the same non-profit organization with the same board of directors. • The parent clinic has submitted the evidence of compliance with the minimum construction standards of adequacy and safety of the affiliate clinic's physical plant. • A letter from a licensed architect or local building authority is received. Also required on the HS 200, Item A.11. 	



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<u>MEDI-CAL CERTIFICATION</u> PRIMARY CARE CLINIC Includes the forms and information required for MEDI-CAL certification			
HS 269	Application for Medi-Cal Certification as a Primary Care Clinic Provider		For Medi-Cal for PCC
HS 328	Notice – Effective Date of Provider Agreement		For Medi-Cal for PCC
DHCS 9098	Medi-Cal Provider Agreement		For Medi-Cal for PCC
	Do not leave any questions blank. Enter N/A, if not applicable. Signature page (page 9) must be notarized.		
<u>MEDICARE CERTIFICATION</u> ONLY APPLIES TO RURAL HEALTH CLINICS Includes the forms and information required for MEDICARE certification NOTE: ONLY SUBMIT THE CMS 29 & HS 610 TO DETERMINE IF YOU QUALIFY AS A RHC			
HS 200	Licensure & Certification Application NOTE: For a RHC that will only be certified Medicare.		
	Refer to the instructions for completion of the HS 200 form found on pages 6-7 of this letter.		
HS 215A	Applicant Individual Information NOTE: For a RHC that will only be certified Medicare.		
	Refer to the instructions for completion of the HS 215A form found on page 8 of this letter.		
HS 309	Administrative Organization and Organizational Structure NOTE: For a RHC that will only be certified Medicare.		
	Refer to the instructions for completion of the HS 309 form found on page 8 of this letter.		
HS 610	Medically Underserved or Health Professional Shortage Areas NOTE: For PCC also applying for RHC Medicare certification -- census tract number.		
CMS 29	Request to Establish Eligibility NOTE: For PCC also applying for RHC Medicare certification.		
CMS 855A	Medicare General Enrollment Health Care Provider/Supplier Application NOTE: For PCC also applying for RHC Medicare certification are required to SUBMIT the CMS 855A.		
	<ul style="list-style-type: none"> • This form is from the Federal Department of Health and Human Services. • The completed forms should be mailed directly to the appropriate Fiscal Intermediary. 		



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CMS 1561A	Health Insurance Benefits Agreement NOTE: For PCC also applying for RHC Medicare certification.		
		<ul style="list-style-type: none"> • SUBMIT two (2) signed copies with "original" signatures. 	
HHS 690	Assurance of Compliance – SUBMIT 2 copies NOTE: For PCC also applying for RHC Medicare certification.		
OMB No. 0990-0243	Civil Rights Information Request for Medicare Certification NOTE: For PCC also applying for RHC Medicare certification		
		<ul style="list-style-type: none"> • Complete and "sign" form (original signature). • SUBMIT required documents for the items checked on this form. 	