



APPLICATION REQUEST FOR A CHRONIC DIALYSIS CLINIC or END-STAGE RENAL DISEASE



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

- Initial application package for a chronic dialysis clinic; or
- Change of ownership (CHOW) application package for a chronic dialysis clinic.

A state license is required to operate a chronic dialysis clinic in California, which is defined as:

Chronic dialysis clinic means a “free-standing specialty clinic, which provides less than 24-hour care for the treatment of patients with End-Stage Renal Disease”.

An application is required for: (1) a new (initial) chronic dialysis clinic; and (2) whenever a CHOW occurs. A CHOW is the only “change” requiring a new application to be submitted to L&C. All other changes (besides a CHOW) must also be reported to the L&C District Office (DO) in writing. 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.

For your convenience, the [attached checklist](#) has instructions to complete the forms required for licensing and/or certification of a chronic dialysis clinic. 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.**

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.



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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 Health & Safety 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 chronic dialysis clinic which is posted on the L&C website at:

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

The application fee will NOT be returned if the application is withdrawn or denied.

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.

All completed chronic dialysis clinic **application packages must be submitted to the local L&C DOs.** The DO will review the application package for completion. A list of DOs and appropriate contacts are located on the L&C website at:

<http://www.cdph.ca.gov/certlic/facilities/Pages/LCDistrictOffices.aspx>

To apply for National Provider Identifier (NPI), go to the following website:

<https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions>

Please NOTE the following:

1. There are some differences between documents required for a CHOW and “initial” application packages that are noted on the attached [checklist](#).
2. An initial **licensing survey** is part of the application process for “new” chronic dialysis clinic facility applications.
3. The initial **licensing survey** is a scheduled survey conducted by L&C DO in the facility.



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4. a. If your facility wants to 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 conducted by one of our L&C DOs.
 - b. If you want the L&C DO to conduct the “initial” certification survey, submit justification to the DO for Centers for Medicare & Medicaid Services approval.
5. In addition, you must be in compliance with state licensing laws and federal conditions of participation.

The DO 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 for very 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 the application is approved and, if required, a successful licensing survey is conducted.

If you have any questions, please contact your local DO administrator located on the DO L&C website listed above.



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Form Number	Item Number on Form	PROVIDER CHECKLIST for a CHRONIC DIALYSIS CLINIC (End-Stage Renal Disease)	Check List
		<p>The following is a quick reference of SOME 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 NOT an all-inclusive list of the questions that need to be answered so read the questions and instructions on each form.</p>	
<p>LICENSURE CHRONIC DIALYSIS CLINIC – END STAGE RENAL DISEASE (ESRD) Includes the forms and information required to be “licensed”</p>			
HS 200	<p>Licensure & Certification Application (H&S Code, Section 1212) NOTE: Please read the instructions on the HS 200 form prior to completion of the form. Also, pay close attention to the following items:</p>		
	A.11.	<p>Construction. SUBMIT the following documents for “initial” applications. N/A for CHOWS, unless there has been construction and/or remodeling.</p> <p>If this is a newly constructed and/or remodeled building, SUBMIT the following:</p> <ol style="list-style-type: none"> 1. Written certification of Title 24 compliance (OSHPD 3 Standards) from a California licensed architect or a local building authority. 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 following form, “<u>Certification Form for Clinics and Freestanding Outpatient Clinic Services of a Hospital</u>” to certify that the facility conforms to current applicable Title 24 California Building Standard Codes (OSHPD 3 Standards). 2. Certificate of Occupancy. <p>If this NOT a previously licensed facility SUBMIT the Title 24 requirements (OSHPD 3 Standards) listed under number 1 (above).</p>	
	B.1.	<p>Licensee’s name. The licensee’s formal organization name must be consistent throughout all documents.</p>	
	B.3.	<p>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:</p>	



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		<ul style="list-style-type: none"> Applicant's owners and their ownership percentages, directors, board members, corporate officers, LLC members/managers, and partners. NOTE: SUBMIT the HS 215A form for each of these individuals. Parent company of applicant, if applicable, and all their licensed agencies/facilities they are operating – See B.6. 	
	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 (parent company) information. If there is a "subsidiary" (parent company) SUBMIT: <ul style="list-style-type: none"> An organization chart with the parent company name. A listing of all owners and their ownership percentages, directors, board members, corporate officers, LLC members/managers, and partners of the parent company. NOTE: SUBMIT the HS 215A form for each of these individuals. A listing of all facilities the parent company is operating. 	
	C.1.a.	Management Company. This question does not apply to chronic dialysis 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. SUBMIT the HS 215A form for the Administrator of the facility.	
	C.6.b.	Director of Nursing.	
	C.7.	Ownership. <ul style="list-style-type: none"> List all individuals having 5% or more ownership, unless "nonprofit". SUBMIT the HS 215A form for each of these individuals. 	
	C.8. thru C.10.	Financial resources, over concentration, and Program Plan approval. These questions are "N/A" for an ESRD facility.	N/A
	D.1. & 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.	



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		Management Company Information. Attachment E-1 does not apply to chronic dialysis clinics.	N/A	
		Signature. "Original" signature is required and MUST be signed by the APPLICANT (not the Administrator).		
HS 215A	Applicant Individual Information NOTE: Please read the instructions on the HS 215A form prior to completion of the form. This form must be completed for the following individuals with ORIGINAL signatures:			
		<ul style="list-style-type: none"> • Administrator of the facility. • Owners, directors, board members, corporate officers, LLC members/managers, and partners of the applicant organization, and/or parent organization. • Each individual having a beneficial interest of 5% or more in the applicant organization and/or parent organization. 		
	Signature	Signature. Original "signature" is required.		
	Facility Information Sheet	Facility Information Sheet. If applicable, each individual must complete and SUBMIT the "Facility Information Sheet" for each facility and/or agency with which they have a <u>current</u> or <u>past</u> relationship within the last 3 years. The following <u>MUST</u> be completed for each facility and/or agency: <ul style="list-style-type: none"> • Facility name • Address of facility • Type of facility • Type of business entity and Employer ID Number (EIN) • Individual's <u>nature</u> of involvement • Individual's dates of involvement • This Sheet must also include any facilities licensed by the California Department of Social Services. 		
HS 309 1 st page	Administrative Organization			
	2.	Administrator of Corporation or LLC – This is usually the CEO/President.		
	3. thru 7.	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> Corporations need to SUBMIT: <ul style="list-style-type: none"> • Copy of Filing Statement from CA Secretary of State (only required if Articles of Incorporation are NOT endorsed by the CA Secretary of State). • Copy of "all" Articles of Incorporation (endorsed by CA Secretary of State). </td> <td style="width: 50%; vertical-align: top;"> LLCs need to SUBMIT: <ul style="list-style-type: none"> • Copy of Filing Statement from CA Secretary of State (only required if Articles of Organization are NOT endorsed by the CA Secretary of State). • Copy of Articles of Organization (endorsed by CA Secretary of State). </td> </tr> </table>	Corporations need to SUBMIT: <ul style="list-style-type: none"> • Copy of Filing Statement from CA Secretary of State (only required if Articles of Incorporation are NOT endorsed by the CA Secretary of State). • Copy of "all" Articles of Incorporation (endorsed by CA Secretary of State). 	LLCs need to SUBMIT: <ul style="list-style-type: none"> • Copy of Filing Statement from CA Secretary of State (only required if Articles of Organization are NOT endorsed by the CA Secretary of State). • Copy of Articles of Organization (endorsed by CA Secretary of State).
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		<ul style="list-style-type: none"> • Copy of By-Laws. • List of board of directors -- SUBMIT the HS 215A form for each individual listed under this item. 	<ul style="list-style-type: none"> • Copy of Operating Agreement. • List of Members / Holders / Officers / Managers – SUBMIT the HS 215A form for each individual listed under this item.
	9.	Governing Board of Directors. Enter the number of members/managers. SUBMIT the HS 215A form for each individual listed under this item.	
	10.	Board Officers and/or LLC Members/Managers. SUBMIT the HS 215A form for each individual listed under this item.	
HS 309 2 nd page	Organizational Structure		
	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 signed Resolution	
	5.	Item 5. Corporations, LLCs and Partnerships need to complete Item 5. N/A for nonprofit.	
	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 each individual listed under this item 	
HS 602	Transfer Agreement Between		
		The Transfer Agreement needs to be current (within one year). Please SUBMIT a copy of the Transfer Agreement.	
STD 850	Fire Safety Inspection		
		<ul style="list-style-type: none"> • The district office will initiate this form. • 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. 	From DO
DHCS 1051	Civil Rights Compliance Review		
		Send directly to Office of Civil Rights – address is on last page of the form.	
CHOW	Change of Ownership		
		<ul style="list-style-type: none"> • SUBMIT all of the forms required for an “initial” application, listed above, plus the following: • Copy of “Purchase Agreement” or “Operating Transfer Agreement”. 	



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		<ul style="list-style-type: none"> 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. 	
<p><u>MEDI-CAL CERTIFICATION</u></p> <p>Only APPLIES TO END STAGE RENAL DISEASE</p> <p>Includes the forms and information required for MEDI-CAL certification</p>			
HS 328	Notice – Effective Date of Provider Agreement		
		If applying for both Medi-Cal & Medicare certification, only need one copy of this form.	
DHCS 9098	Medi-Cal Provider Agreement		
		<ul style="list-style-type: none"> Do not leave any questions blank. Enter N/A or “same” if not applicable. The “mailing address” must be the same as reported on the HS 200 form. Signature page (page 9) must be notarized. SUBMIT the “Acknowledgement” page from the Notary Public, if applicable. 	
<p><u>MEDICARE CERTIFICATION</u></p> <p>Only APPLIES TO END STAGE RENAL DISEASE</p> <p>Includes the forms and information required for MEDICARE certification</p>			
HS 328	Notice – Effective Date of Provider Agreement		
		If applying for both Medi-Cal & Medicare certification, only need one copy of this form.	
CMS 855A	Medicare General Enrollment Health Care Provider/Supplier Application		
		This form is available from the Federal “Department of Health and Human Services”. The completed form should be mailed directly to the appropriate Fiscal Intermediary.	
CMS 3427	End-Stage Renal Disease Application/Notification and Survey and Certification Report		
		The applicant will need to complete and provide all information that they have on Sections 1 thru 24 (except #2). The surveyor will bring a copy of this form to the facility to update and add additional information, when the certification survey is conducted.	



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BUSINESS PLAN LETTER	Business Plan Letter	SUBMIT a <u>business plan</u> letter explaining (with detailed information) your "Business Plan" for operation of the ESRD, including a description of all services to be provided.	