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 Centralized Applications Unit (CAU) in writing. These other changes do not require submittal of a new application package. The CAU 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.

Submission of Applications

All completed 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.

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 CLHF 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.

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.
Application Request for an Chronic Dialysis Clinic (CDC) or End-Stage Renal Disease (ESRD) Facilities

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


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 district office (DO) in the facility.
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.

Except for the Los Angeles (LA) facilities, the DO will notify you (via letter) when the application has been approved by CAU and will schedule an “initial” licensing survey. For the LA facilities, the CAU will notify you (via letter) 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: An “initial” 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 the CAU, at (916) 552-8632 or by e-mail at CAU@cdph.ca.gov.
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.

### Licensure

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<tbody>
<tr>
<td>HS 200</td>
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<td><strong>Licensure &amp; Certification Application (H&amp;S Code, Section 1212)</strong> Note: Please read the instructions on the HS 200 form prior to completion of the form. The items listed below are the most common items that are not completed correctly – however, these are not all of the items listed on each form.</td>
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|        | A.11.  | **Construction.** 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:  
  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:  
    • California Building Code  
    • California Electrical Code  
    • California Mechanical Code  
    • California Plumbing Code  
    or  
    • The California licensed architect or local building authority may use the following form, “Certification Form for Clinics and Freestanding Outpatient Clinic Services of a Hospital” to certify that the facility conforms to current applicable Title 24 California Building Standard Codes (OSHPD 3 Standards).  
  2. Certificate of Occupancy. If this not a previously licensed facility submit the Title 24 requirements (OSHPD 3 Standards) listed under number 1 (above). |            |
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| HS 200 (cont.) | B.1. | Licensee’s name.  
The licensee’s formal organization name must be consistent throughout all documents.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |            |
|       | 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:  
• Applicant’s owners, 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 of the 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |            |
If there is a “subsidiary” (parent company) submit:  
• An organization chart with the parent company name.  
• A listing of all owners, directors, board members, corporate officers, LLC members/managers, and partners of the parent company. [H&S Code, Section 1265(i)]  
  **Note:** Submit the HS 215A form for each of these individuals.  
• A listing of all facilities the parent company is operating.                                                                                                                                                                                                                                                                                                                                       |            |
## Application Request for an Chronic Dialysis Clinic (CDC) or End-Stage Renal Disease (ESRD) Facilities

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| HS 200 (cont.) | 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. |  |
- Submit the HS 215A form for the Administrator of the facility. |  |
| | C.6.b. | Director of Nursing. |  |
| | C.7. | Ownership.  
- List all individuals having 5% or more ownership, unless “nonprofit”.  
- Submit the HS 215A form for each of these individuals. |  |
| | C.8. - C.10. | Financial resources, over concentration, and Program Plan approval.  
- These questions are “N/A” for an ESRD facility. | N/A  |
| | D.1. | 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. |  |
| | F.1. | Signature.  
- “Original” signature is required and must be signed by the applicant (not the Administrator). |  |
### Application Request for an Chronic Dialysis Clinic (CDC) or End-Stage Renal Disease (ESRD) Facilities

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| HS 215A | | Applicant Individual Information (H&S Code, Section 1267.5)  
**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:  
- Administrator of the facility  
- Owners, directors, board members, corporate officers, LLC members/managers, and partners of the applicant and parent organization.  
- Each individual having a beneficial interest of 5% or more in the applicant organization and/or parent organization.  
[H&S Code, Section 1267.5(a)(1)] | |
| | Sign | Signature.  
- Original “signature” is required | |
| Fac Info 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 current or past relationship within the last 3 years. The following must be completed for each facility and/or agency:  
- Facility name  
- Address of facility  
- Type of facility  
- Type of business entity and Employer ID Number (EIN)  
- Individual’s nature of involvement  
- Individual’s dates of involvement  
- This Sheet must also include any facilities licensed by the California Department of Social Services. | |
### Application Request for an Chronic Dialysis Clinic (CDC) or End-Stage Renal Disease (ESRD) Facilities

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<tr>
<td>HS 309 1st page</td>
<td>2.</td>
<td>Administrator of Corporation or LLC – This is usually the CEO/President.</td>
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</table>
| | 3. – 7. | Corporations need to submit:  
- Copy of the 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).  
- Copy of By-Laws.  
- List of board of directors – submit the HS 215A form for each individual listed under this item. | | |
| | | LLCs need to submit:  
- Copy of the Filing Statement from CA Secretary of State (only required if Articles of Organization are not endorsed by the CA Secretary of State).  
- Copy of all Articles of Organization (endorsed by CA Secretary of State).  
- 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. | | |
| | 10. | Board Officers and/or LLC Members/Managers.  
- Submit the HS 215A form for each individual listed under this item. | | |
| HS 309 2nd page | 1. | California Out-of-State Corporations, LLC, etc.  
- Submit a copy of the Certificate of Qualification from the California Secretary of State | | |
- Submit a copy of the signed Resolution | | |
| | 5. | Corporations, LLCs, and Partnerships need to complete. N/A for nonprofit. | | |
| Bottom of page | | Partnerships need to submit:  
- A copy of the Partnership Agreement  
- Copy of the California Secretary of State filing  
- HS 215A form for each individual listed under this item | |
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| HS 602 |        | Transfer Agreement Between  
        • Please submit a copy of the Transfer Agreement. The Transfer Agreement needs to be current (within one year). | |
| STD 850 |        | Fire Safety Inspection Request  
        • 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. | |
| 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  
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. | |
## Medi-Cal Certification
Only applies to End Stage Renal Disease
Includes the forms and information required for Medi-Cal certification

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| 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  
- 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. | |

## Medicare Certification
Only applies to End Stage Renal Disease
Includes the forms and information required for Medicare certification

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| 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). **Note:** The surveyor will bring a copy of this form to the facility to update and add additional information, when the certification survey is conducted. | |
| Business Plan Letter | | Business Plan Letter  
- Submit a business plan letter explaining (with detailed information) your “Business Plan” for operation of the ESRD, including a description of all services to be provided. | |