How to Become a Licensed End Stage Renal Disease Facility

Attached is an application packet for an Initial, Relocation, or Change of Ownership (CHOW) License for an End Stage Renal Disease Facility. The application, fees, and other documents shall be submitted as required by 25 Texas Administrative Code, Chapter 117, End Stage Renal Disease Facility Licensing Rules, §117.12 Application and Issuance of Initial License. Information regarding licensure for health care facilities, including contact information for the Health Facility Compliance Zone Office for your location is located on the department’s website at http://www.dshs.texas.gov/facilities.

The following documents, fees, and actions shall be completed and approved before a license will be issued:

Initial Application

- A license application form submitted approximately 90 calendar days prior to the projected opening date of the facility.
- A license fee ranging from $3,500.00 - $6,700.00 based on total number of stations shall be submitted. Refer to the license application to determine required fee. **License fees are not refundable.**
- A written plan for the orderly transfer of care of patients and clinical records in the event the facility is unable to maintain services under the license.
- A completed Fire Safety Survey Report form shall be submitted. Annual fire safety inspections are required for continued licensure status. Include a copy of a fire inspection report conducted within the last 12 months indicating approval by the local fire authority.
- Approval for occupancy shall be obtained from the Architectural Review Group: (512) 834-6649 or http://www.dshs.texas.gov/facilities/architectural-review.aspx).
- The administrator or a licensed professional who is listed on the license application shall attend a presurvey conference at the Health Facility Compliance Zone Office designated by the department. Contact the designated office to schedule the presurvey conference (http://www.dshs.texas.gov/facilities/compliance-zones.aspx).
- The facility shall submit a complete chemical analysis of the product water, and reports to verify that bacteriological and endotoxin levels of product water and dialysate are in compliance with §117.32 (relating to Water Treatment, Dialysate Concentrates, and Reuse). Reports shall be submitted to the designated Health Facility Compliance Zone Office.
for approval. Contact the designated office with any questions.


**Relocation Application**

- A license application form submitted approximately 90 calendar days prior to the projected opening date of the facility.
- A license fee ranging from $3,500.00 - $6,700.00 based on total number of stations shall be submitted. Refer to the license application to determine required fee. **License fees are not refundable.**
- A written plan for the orderly transfer of care of patients and clinical records in the event the facility is unable to maintain services under the license.
- A completed Fire Safety Survey Report form shall be submitted. Annual fire safety inspections are required for continued licensure status. Include a copy of a fire inspection report conducted within the last 12 months indicating approval by the local fire authority.
- The facility shall submit a complete chemical analysis of the product water, and reports to verify that bacteriological and endotoxin levels of product water and dialysate are in compliance with §117.32 (relating to Water Treatment, Dialysate Concentrates, and Reuse). Reports shall be submitted to the designated Health Facility Compliance Zone Office for approval. Contact the designated office with any questions.

**Change of Ownership (CHOW) Application**

- A license application form to be submitted at least 60 calendar days before the date of the change of ownership.
- A license fee ranging from $3,500.00 - $6,700.00 based on total number of stations shall be submitted. Refer to the license application to determine required fee. **License fees are not refundable.**
- A written plan for the orderly transfer of care of patients and clinical records in the event the facility is unable to maintain services under the license.
- A copy of two completed Fire Safety Survey Report forms shall be submitted. Annual fire safety inspections are required for continued licensure status. Include a copy of a fire inspection report conducted within the last 12 months and a second report conducted within the last 13 to 24 months indicating approval by the local fire authority.
• The administrator or a licensed professional who is listed on the license application shall attend a presurvey conference at the Health Facility Compliance Zone Office designated by the department. Contact the designated zone office to schedule the presurvey conference or to request a waiver (http://www.dshs.texas.gov/facilities/compliance-zones.aspx).

• Medicare certified facilities shall complete the Life Safety Code Attestation available on our website at http://www.dshs.texas.gov/facilities/esrd/forms.aspx or agree to have a Life Safety Code survey at a later date.

• The applicant shall include evidence (Bill of Sale, lease agreement, or legal court document) of the Change of Ownership. This document can be submitted separately from the license application.

**Important Items to Note:**

• The D/B/A or Assumed name of the facility is the name that will appear on the license and should match advertisements and signage of the facility.

• The Legal Name and EIN on the application should be an exact match with the IRS letter, Secretary of State documentation, and ownership structure.

• The ownership structure should reflect all levels of ownership and include EIN numbers. The chart should start with the D/B/A or Assumed Name, continue with the Legal Name, and end with any additional ownership levels. An example has been attached for your reference.

**Additional Information:**

Medicare certification information may be obtained from the Health Facility Compliance Zone Office for your location (http://www.dshs.texas.gov/facilities/compliance-zones.aspx). The Social Security Act directs the Secretary of the Department of Health and Human Services to use the help of State health agencies or other appropriate agencies to determine if health care entities meet Federal standards. This task is one of the Texas Health and Human Services Commission’s responsibilities. For information on gaining provider certification, contact Zone Office staff.

CLIA information is located on the department’s website at http://www.dshs.texas.gov/facilities/clia.aspx. For more information, contact the Health Facility Compliance Zone Office for your location.
The Facility Licensing Group is dedicated to assist you through this process and is available to answer your questions. If you have any questions, contact the Facility Licensing Group: phone (512) 834-6646, fax (512) 834-4514.

**MAILING ADDRESS:**
HHSC AR
P.O. BOX 149055
Austin, Texas 78714-9055
EXAMPLE
OWNERSHIP STRUCTURE

HIGHER LEVEL
OF OWNERSHIP

EIN #

(Add Boxes as Needed)

LEGAL NAME

EIN #

DOING BUSINESS AS (D/B/A)
or ASSUMED NAME
END STAGE RENAL DISEASE FACILITY LICENSE APPLICATION

☐ Initial
Projected date facility will open: __________ Architectural Project #: __________

☐ Change of Ownership
Effective Date: __________ Current License #: __________

☐ Relocation
Projected Date Facility Will Open: __________
Current License #: __________ Architectural Project #: __________

1. Facility Information:

a. Name the facility will be Doing Business As (D/B/A) or Assumed Name:

This is the name that will appear on the license and should match advertisements and signage of the facility.

b. Street Address:

Address

City/State/Zip County

c. Mailing Address:

Street Address or P.O. Box Number

City/State/Zip

d. Telephone Number

e. Fax Number

Leave blank if numbers are unknown at this time.
2. Ownership Information:

a. Legal Name
Name of legal entity directly responsible for day to day operation of the facility.

b. Mailing Address
City/State/Zip

c. EIN Number
d. Telephone Number
e. Email Address

f. Provide a copy of the IRS letter assigning the employer identification number (EIN).

g. Provide a copy of the Certificate of Filing from the Office of the Secretary of State.

h. Attach an ownership structure. See Example.

i. Status: □ Profit  □ Non-Profit

j. Type of Legal Entity:
- □ City
- □ Corporation
- □ County
- □ Hospital
- □ LTD
- □ Sole Owner/Proprietorship
- □ State
- □ Other: ____________________________________

3. Ownership and Control Interest Disclosure:

a. The owner/legal entity must disclose the following data for the two-year period preceding the application date. Check yes or no to the following questions. If yes is checked, you must provide details, including ownership and facility information, circumstances, dates and final action, on a separate sheet with this application.

1. Eviction involving any property used as a health care facility in any state?  Yes □ No □
2. Federal or state (any state) tax liens? Yes □ No □
3. Unsatisfied final judgments? Yes □ No □
4. Federal or state (any state) criminal misdemeanor arrests or convictions? Yes □ No □
5. Injunctive orders from any court? Yes □ No □
6. Unresolved final state or federal Medicare or Medicaid audit exceptions? Yes □ No □
b. The owner/legal entity must disclose the following data. Check yes or no to each question. If yes is checked, provide details on a separate sheet, including all ownership and facility information, circumstances, dates and final action.

1. Denial, suspension, or revocation of end stage renal disease license or any health agency in any state or any other enforcement action?  Yes ☐ No ☐
2. Denial, suspension, revocation, or other enforcement action against a health care facility licensed in any state, which is or was proposed by the licensing agency and the status of the proposal? Yes ☐ No ☐
3. Surrendered a license before expiration of the license or allowing a license to expire in lieu of the department proceeding with enforcement action? Yes ☐ No ☐
4. Federal or state (any state) criminal felony arrests or convictions? Yes ☐ No ☐
5. Federal or state Medicaid or Medicare sanctions or penalties relating to the operation of a health care facility? Yes ☐ No ☐
6. Operating a health care facility that has been decertified with Medicare or Medicaid? Yes ☐ No ☐
7. Debarment, exclusion, or contract cancellation from Medicare or Medicaid in any state? Yes ☐ No ☐

4. Personnel:
Provide names, license numbers and expiration dates for each of the following individuals:

a. Board Certified Medical Director:

<table>
<thead>
<tr>
<th>Name</th>
<th>License #</th>
<th>Expiration Date</th>
</tr>
</thead>
</table>

b. Supervising Nurse:

<table>
<thead>
<tr>
<th>Name</th>
<th>License #</th>
<th>Expiration Date</th>
</tr>
</thead>
</table>

c. Social Worker:

<table>
<thead>
<tr>
<th>Name</th>
<th>License #</th>
<th>Expiration Date</th>
</tr>
</thead>
</table>

d. Dietitian:

<table>
<thead>
<tr>
<th>Name</th>
<th>License #</th>
<th>Expiration Date</th>
</tr>
</thead>
</table>
5. Dialysis Services:
   a. □ Adult Only
      □ Pediatric Only
      □ Pediatric and Adult
   b. □ In-center Hemodialysis
      □ Home Hemodialysis
      □ Home Peritoneal
   c. □ Isolation room
      □ CMS Waiver for the Isolation Room
      □ Separate Isolation Area*
      □ Transfer Agreement*
      □ None (Home Training Only Facilities)

*If the application is for a CHOW for a facility licensed prior to February 9, 2009, this may be chosen.

6. Dialysis Stations:
   Station changes require prior DSHS approval.

   Number of in-center hemodialysis stations: __________
   Number of isolation stations: __________
   Number of hemodialysis training stations: __________
   Number of peritoneal training stations: __________
   Number of dual use hemodialysis & peritoneal training stations: __________
   **Total number of stations:** __________

7. License Fee: License fee not required if facility is operated by the State of Texas.

   Initial/Relocation/Change of Ownership:
   1-10 stations = $3,500.00
   11-20 stations = $4,300.00
   21-30 stations = $5,100.00
   31-40 stations = $5,900.00
   41 or more stations = $6,700.00

   Make checks payable to the Texas Health and Human Services Commission.
   Fees paid to the Department are not refundable.

8. Dialysis Technicians (check appropriate box):

   □ Each dialysis technician on staff in the facility has completed the training and competency evaluation programs described in 25 TAC §117.62 and 117.63.

   □ This facility does not use dialysis technicians.
9. Additional Required Documents:

☐ Fire Safety Survey - A completed Fire Safety Survey Report form shall be submitted. Include a copy of a fire inspection report conducted within the last 12 months indicating approval by the local fire authority. For change of ownership applications, a copy of two completed Fire Safety Survey Report forms shall be submitted; one report dated within the last 12 months and a second report dated within the last 13 to 24 months.

☐ A written plan for the orderly transfer of care of patients and clinical records in the event the facility is unable to maintain services under the license.

☐ Life Safety Code Attestation

☐ Floor plan which includes each station identified *(CHOW application only)*

☐ Bill of Sale *(CHOW application only; can be submitted separately from application)*

10. Administrator’s Signature:

The administrator attests that the owner is capable of meeting the requirements of 25 Texas Administrative Code, Chapter 117, End Stage Renal Disease Facilities. The administrator attests that all information contained in this application is true and correct. The administrator attests that all copies submitted with the application are original copies or copies of the original documents. The administrator attests that if a change of ownership has occurred, the new owner shall be responsible for previous regulatory violations and shall ensure compliance with all rules and regulations.

_________________________________________  ______________________________________
Administrator’s Name *(Print)*                Title

*Person responsible for day-to-day operations at the facility*

_________________________________________  ______________________________________
Administrator’s Signature                      Date Signed

_________________________________________  ______________________________________
Administrator’s Email Address                  Administrator’s Telephone Number

11. Contact Person:

_________________________________________  ______________________________________
Name of the person completing this application  Title

_________________________________________  ______________________________________
Telephone Number                             Email Address