BACKGROUND:
The Healthcare Regulation and Quality Improvement program ensures that a safe and healthy
environment is provided by over 500 health related facilities and agencies. SB 158 was passed by
the 2009 Oregon Legislature, to update the Dialysis facility licensure regulation and application fees.
Permanent administrative rules have been filed to address the provisions of SB 158, as well as,
aligning the current rules with federal guidelines.

SUMMARY OF CHANGES:
These rules address new fees for ORDF licensing, classification of ORDFs, inspections, complaint
investigations, building requirements, staffing ratios and mobile dialysis.

ORDF Fees (UPDATED)
Effective January 1, 2010 new fees are in effect for licensing of ORDF's:

- $2,000 for initial, renewal, and change of ownership.

Civil Penalties (UPDATED)
A licensee that violates a health care facility licensing law is subject to the imposition of a civil
penalty not to exceed $500 per day per violation.

In determining the amount of a civil penalty the Division shall consider whether:

- The Division made repeated attempts to obtain compliance;
- The licensee has a history of noncompliance with health care facility licensing laws;
- The violation poses a serious risk to the public's health;
- The licensee gained financially from the noncompliance; and
- There are mitigating factors, such as a licensee's cooperation with an investigation or actions
to come into compliance.

The Division shall document its consideration of the factors in section (3) of this rule. Each day a
violation continues is an additional violation.

Waivers (UPDATED)
Outpatient renal dialysis facilities are required to remain in compliance with the Division’s rules at all
times. However, a facility can request a waiver from an administrative rule. A request for a waiver
from a rule must be:

- Submitted to the Division in writing;
- Identify the specific rule for which a waiver is requested;
- The special circumstances relied upon to justify the waiver;
- Why the facility is unable to be in compliance, the alternatives considered and why the
alternatives were not selected;
- Demonstrate that the proposed waiver is desirable to maintain or improve the health and
safety of the patients, to meet the individual and aggregate needs of patients, and shall not
jeopardize patient health and safety; and
- The proposed duration of the waiver.
The division may or may not grant the waiver, but will notify the facility of the decision. A facility may not implement a waiver until it has received written approval from the Division. You may find a waiver form online at www.healthoregon.org/hcrqi

**Outpatient Mobile Dialysis (NEW Service)**

A dialysis facility that provides outpatient mobile dialysis must:

- Be licensed as an outpatient renal dialysis facility; and
- Have a centralized, secure location, where the patient, water quality, equipment maintenance, quality assurance and other records are available for review by the Division.

A facility must obtain written approval from the Authority prior to implementation of the provision of outpatient mobile dialysis services. The Authority may conduct a survey to determine compliance with this rule.

Hemodialysis treatments must be performed by an individual currently licensed or certified in Oregon as a certified hemodialysis technician, registered nurse or licensed practical nurse who:

- Has at least six months of experience in caring for hemodialysis patients; and
- Has completed, prior to providing assisted hemodialysis treatments in a patient's home, a training program and skills checklist specific to care of hemodialysis patients in the patient’s home and management of complications.

The dialysis facility RN responsible for patient care shall ensure that individuals performing hemodialysis in a patient’s home meet the qualifications above and shall document such qualifications and provide the documentation to the Division upon request. The facility must ensure that the water and dialysate testing and other requirements of American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) RD52:2004 are met. In addition, bacteriological and endotoxin testing must be performed on a quarterly or more frequent basis as needed, to ensure that the quality of the water and dialysate meets these AAMI requirements.

The dialysis facility must correct any water and dialysate quality problems for the home hemodialysis patient.

- A record of any preventive hemodialysis machine maintenance as required by the manufacturer's directions for use must be maintained and any breakdowns repaired; and
- The facility must arrange for backup dialysis until water quality and mechanical problems are corrected.

If staff assisted outpatient mobile dialysis is provided in a health care facility providing 24/7 onsite nursing services the following additional requirement must be met:

- The staffing ratio for staff assisted home dialysis must be one licensed nurse or Certified Hemodialysis Technician per patient unless the following conditions are met:
  - The patients are located in one room in which they are visible from a central location within that room; and
  - (B) There is a second staff member, who is a registered nurse, with at least six months dialysis experience.
- Should the requirements above be met, the staffing ratio must be dependent on the acuity and needs of the patients as determined by the dialysis facility RN or the patient's nephrologist.
• In no case shall the staffing ratio be greater than three patients per one qualified staff member while patients are undergoing hemodialysis treatments.
• There must be an agreement between the dialysis facility and the care facility specifying the expectations of each party, to ensure the coordination of individual patient care needs.
• Policies and procedures regarding care of the hemodialysis patient must be in place for both the care facility and dialysis facility.
• If the staff assisted hemodialysis is performed by a CHDT there must be an RN on duty, and accessible, in the care facility who has documented training in the care of hemodialysis patients including, but not limited to, common ESRD related medications, IV medications commonly given during dialysis, potential complications of hemodialysis, assessment of ESRD patients, and treatment of those complications. This training shall be updated annually.
• There must be documentation reflecting that:
  o On the day of dialysis prior to the initiation of the hemodialysis treatment, the care facility RN has assessed the patient and consulted with the dialysis facility RN; and
  o The CHDT providing the hemodialysis treatment must consult with the care facility RN before and after the hemodialysis treatment.
• The dialysis facility RN must be available at all times for consultation while the patient is undergoing hemodialysis treatment.

**Patient Care Staff-Staffing Ratio (NEW Requirements)**
An adequate number of personnel must be present to ensure that the staff/patient ratio is appropriate to the level of dialysis care being provided. The staffing levels must be adjusted based on the individual and aggregate needs of the patients.

• At a minimum, the staffing level at a facility shall not exceed four patients receiving hemodialysis treatments per licensed nurse or CHDT providing direct patient care.
• During treatment times, there shall be a minimum of one registered nurse (RN) available for every 16 patients.
• If more than 16 patients are receiving hemodialysis treatments at one time, there shall be an additional registered nurse present.
• Should the RN to patient ratio exceed 1 to 12, the RN shall not be counted as part of the 1 to 4 direct patient care ratio.
• The facility shall have a staffing plan in place that shall allow them to maintain staffing ratios in the event of sick calls, vacations and unscheduled absences.
• The facility may continue to operate and treat scheduled patients in the event that circumstances temporarily do not allow these staffing levels to be met if the medical director or designee determines this can be done safely:
  o These circumstances shall be documented in the records of the facility; and
  o These circumstances must not occur during more than five percent of the facility's operating hours in any six month period without approval of a waiver by the Division.
• These staffing ratios do not preclude the use of new technology or experimental models.
• Application for a waiver may be made to the Division by facilities wishing to implement new technology.

**Dialysis Facilities Construction (NEW Requirements)**
In order to comply with state and federal standards, several construction requirements have been added or changed. If you would like more information on this topic please visit the Facilities Planning and Safety website at [www.healthoregon.org/fps](http://www.healthoregon.org/fps). This is a summary of the changes:

• All plans submitted after the effective date of these rules will be subject to the new construction requirements.
Treatment Areas:

- Dialysis stations must have one hand washing station must be provided for each four patients minimum.
- Provide an Isolation Room (to prevent contact transmission of the infectious material) meeting the following minimum criteria:
  - Shall provide a door and walls that go to the floor, but not necessarily the ceiling, and allow for visual monitoring of the patient;
  - Shall accommodate only one patient; and
  - Shall contain a hand washing station located in each patient room.

General Support Areas:

- Clean supply room with space for bulk storage of necessary supplies. If preparation of patient care supplies happens within the room, then the clean room must contain a hand wash sink and work counter;
- Soiled holding room or area for medical waste. A work counter and hand washing station shall be provided. A flush rim clinical sink with rinsing device is also required when peritoneal dialysis is performed;
- Separate staff toilet, including hand washing station within or near the treatment area;
- If a home training program is included, the following shall be provided: separate, 120 square foot, training room(s) each with a hand washing station, counter and separate drain for fluid disposal. At least one convenient program office and general support spaces shall be provided to meet program needs. An emergency nurse call, annunciator at the patient care staff station, or the home training office, shall be provided in each training room.

Mechanical and Plumbing:

- All heating, ventilation and cooling systems shall comply with the Oregon Mechanical Specialty Code as enforced by the Oregon Building Codes Division or local jurisdiction having authority and shall be maintained in full compliance;
- Hot water used for hand washing shall have a water temperature of a minimum of 105° and a maximum of 120° Fahrenheit;
- All water treatment and dialysate concentrate equipment and distribution systems shall be in compliance with Association for the Advancement of Medical Instrumentation (AAMI) standards (RD52) at all times. Floor drain(s) shall be provided in these area(s);
  - No dead end loops or unused branches are allowed in the purified water distribution system;
  - Product water distribution system shall be constructed of materials that do not contribute chemicals, such as aluminum, copper, lead, and zinc or bacterial contaminants to the purified water.
  - When used, storage tanks shall have a conical or bowl shaped base and shall drain from the lowest point of the base.
- In facilities licensed after July 1, 2003, lavatories and sinks intended for hand washing shall be trimmed with fittings operable without use of the hands. Wrist blade controls are not considered to be operable without the use of hands.
Electrical:

- All electrical installations shall comply with the Oregon Electrical Specialty Code as enforced by the Oregon Building Codes Division or local authority having jurisdiction and shall be maintained in full compliance.
- Emergency power for evacuation lighting, the fire alarm system and the dedicated receptacle for the emergency cart, shall be provided. Lighting levels shall be five foot candles minimum at patient stations, staff support stations and paths of egress for a minimum of 1-1/2 hours.

Structural, Fire & Life Safety and Maintenance:

- Dialysis facilities shall be located on the ground floor, unless they are considered an Institutional, I-2, occupancy class per the Oregon Structural Specialty Code and, if certified by Centers for Medicare and Medicaid, an Ambulatory Health Care Occupancy per the National Fire Protection Association Life Safety code 101.

Questions? Contact the HCRQI program at 971-673-0540 or by email at mailbox.hclc@state.or.us