

Note: Outpatient Peritoneal Dialysis facilities must adhere to all DSHS ESRD Facility Licensure Rules, as published by the Department of State Health Services Health Facility Licensing and Compliance Division and effective May 9, 2004 with the exception of Licensure Rules specific to hemodialysis facilities listed on page 12 of this document.

Standard I: Design and Space Requirements

The facility will provide designated areas of adequate size to accommodate the flow of patients and family members during PD training and PD clinic visits.

Measurement Criteria

- A. Facility has a patient waiting room with seating and a reception or information counter/desk that is a separate area and is not used for PD training, clinic visits, procedures or exams.

- B. The facility shall provide at least one PD training area separate from the clinic area.

- C. The PD training area:
 - 1. Contains at least 110 square feet of usable space.
 - 2. Provides ample space for movement and dialysis equipment/supplies.
 - 3. Provides an area that is removed from clinic traffic patterns.
 - 4. Is designed and equipped to facilitate a safe, quiet learning environment.
 - 5. Has either a door that can be closed (that does not lock from the inside) or a curtain that can be drawn to assure privacy during training sessions.
 - 6. Provides sufficient lighting for all PD learners, including those with visual impairment.
 - 7. Has readily accessible hand washing (clean) sinks in each PD training room.
 - 8. Provides for safe, splash-proof disposal of PD effluent through a dedicated drain line or effluent disposal station (separate from the clean hand washing sink) in the training area.
 - 9. Provides an area that is free from drafts from ceiling ventilation drafts, fans, external windows or doors. Alternately the training area could be equipped with a control to turn off heat/air flow in the room.
 - 10. Is equipped with a "Do Not Disturb" sign for the training room door.

Standard II: Equipment

The facility will meet the medical, dialysis and safety needs of each PD patient through the provision and maintenance of both clinic-based equipment and dialysis-related equipment being utilized in the home setting.

Measurement Criteria

- A. Patients will be trained on the specific machine model that they will be using at home. Whenever possible, patients with an automated peritoneal dialysis prescription (APD) or overnight exchange device are trained with the individual machine that will accompany them to their home.
- B. Only individuals qualified by training operate, repair or replace components of the systems utilized for peritoneal dialysis treatments.
- C. Facility provides (or contracts the provision of) routine maintenance, per manufacturer's recommendations, for all peritoneal dialysis-related equipment being utilized in the home setting.
- D. Facility staff assist patients and family members in ordering and maintaining an inventory of dialysis-related supplies for the home.
- E. Facility staff instruct patients and family members on proper storage of dialysis-related equipment and supplies.
- F. Facility provides patient and family members with routine and emergency maintenance contact information, in case of dialysis equipment malfunction.
- G. Facility staff assist patients who wish to travel in making arrangements for obtaining and/or shipping dialysis supplies and equipment to their destination(s).
- H. Facility emergency equipment receives routine maintenance and periodic testing to assure proper functioning and replace expired supplies and medications.
- I. If pediatric patients are treated, a facility uses equipment and supplies, to include blood pressure cuffs, dialysate bags and tubing and dialysis equipment, appropriate for this special population.

Standard III: Sanitary Conditions, Hygienic Practices and Infection Control

The facility will protect the safety and well being of patients and staff through the implementation and maintenance of recommended infection control policies and procedures and proper medical waste and liquid/sewage waste management.

Measurement Criteria

- A. Facility has readily accessible hand washing (clean) sinks outside the training room(s). These sinks are not utilized for effluent disposal.
- B. Facility provides at least one splash proof "effluent disposal station" outside the training room(s).
- C. Facility performs daily cleaning and/or flushing of effluent disposal stations being utilized in the training rooms and outside the training rooms, with an appropriate chemical disinfectant.
 - 1. If a solution of chlorine bleach (sodium hypochlorite) is used, the solution shall be at least 1:100 sodium hypochlorite and the surface to be treated must be compatible with this type of chemical treatment.
- D. Ceiling tiles stained with blood or body fluids are cleaned or replaced.
- E. Blood and/or body fluid spills (including PD effluent) are cleaned immediately with an appropriate chemical disinfectant.
 - 1. If a solution of chlorine bleach (sodium hypochlorite) is used, the solution shall be at least 1:100 sodium hypochlorite and the surface to be treated must be compatible with this type of chemical treatment.
- F. Facility staff follow recommended handling and disposal procedures for medical waste supplies (per institution policy, manufacture recommendations or city/state guidelines).
- G. PD home patients and family members are instructed in safe handling and disposal of medical waste supplies (PD effluent, PD bags, tubing, needles, syringes) in the home or residential setting.
- H. Facility cleans machine exteriors (if applicable), treatment chairs, table surfaces, blood pressure cuffs, tourniquets, etc. between home training or clinic patients.

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- I. Blood pressure cuffs which become contaminated with body fluids or secretions are removed from service, disinfected and allowed to dry prior to being return to use.
- J. Universal precautions are observed with all PD patients and are sufficient for HbsAg+ PD patients.
- K. Staff are instructed:
 1. To **discourage** disposal of effluent from HbsAg+ PD patients in the facility's effluent disposal stations.
 2. To **encourage** HbsAg+ patients to dispose of their effluent when they return home.
 3. If effluent from HbsAg+ patients **must** be disposed of in any of the facility's effluent disposal stations, the internal lumen of the effluent disposal station is immediately flushed with a bleach solution of at least 1:100 sodium hypochlorite.
- L. Patients with medical history or symptoms suggestive of undiagnosed active pulmonary tuberculosis are promptly referred to a facility or hospital that has TB isolation capacity.
 1. When possible, elective PD procedures (non-emergent blood draws, PET, routine transfer set changes, etc.) are deferred until the patient is no longer infectious.
 2. If urgent PD care is needed (contaminated transfer set, treatment of peritonitis), PD staff uses recommended respiratory precautions while performing the procedure, including the wearing of surgical mask by patient and staff member.

Standard IV: Quality Assurance for Patient Care

Quality management activities shall demonstrate that facility staff monitor, trend and evaluate the provision of dialysis care and patient services.

Measurement Criteria

- A. Facility collects, trends and monitors aggregate clinical patient data and clinical outcomes on an ongoing basis according to the frequency below:
 1. For new patients initiating PD:
 - Adequacy measurement 1 month following initiation of PD.
 - Following initial adequacy measurement, adequacy testing should be performed and monitored as needed until patient reaches goal.

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- Baseline testing for Evaluating Peritoneal Membrane Transport/Function should be performed and reviewed at 4-8 weeks after initiation of PD when patient is stable.
 - 2. Monthly collection, trending and monitoring:
 - Laboratory indicators for anemia management, osteo-dystrophy management, albumin management
 - Exit site infection rate
 - Catheter tunnel infection rate
 - Sepsis
 - Other infections
 - Peritonitis rate
 - Vascular access complications (if patient has a HD access).
 - 3. Quarterly collection, trending and monitoring:
 - Laboratory indicators for adequacy
 - Mortality rate
 - Hospitalization rate
 - Transplantation rate
 - 4. Annual collection, trending and monitoring:
 - PD Catheter Complications (infectious and non-infectious)
 - PD dropout rate
- B. Facility collects, trends and monitors infection control practices on an ongoing basis, including staff and patient screening.
- C. QM meetings scheduled per DSHS Licensure Rules and attended by patient's physician, facility administrator, PD nurse manager, social worker and dietitian.
- D. Prior to accepting patients, PD facilities schedule an initial QI consult (by phone or face to face) with ESRD Network QI staff.

Standard V: Provision and Coordination of Treatment and Services

On an ongoing basis, the facility shall provide and/or coordinate treatment and services for the home peritoneal dialysis patient that promotes safe, effective and timely kidney replacement therapy.

Measurement Criteria

- A. Scope of provision and coordination of treatment and services includes, but is not limited to:
- 1. Modality education reinforcement.
 - 2. Assessment of potential candidates.
 - 3. Provision of initial PD home training.

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4. Provision of reinforcement education on an ongoing basis.
 5. Home visits.
 6. Scheduling of routine and non-routine clinic visits and laboratory tests.
 7. Provision of erythropoietin-stimulating agent (ESA) and iron therapy (if applicable).
 8. Policy that facilitates safe, effective coordination of dialysis therapy during hospitalization, including options available to patient/family.
 9. Assists patient and family member in coordination of "back-up" hemodialysis treatments when indicated.
 10. Education about palliative care when indicated.
- B. Facility hours of operation allow patients to access the clinic and PD Nurse during the day during the week (Monday-Friday).
- C. Facility provides patients with a system that allows them to access the PD Nurse or their physician on 24-hour/per day basis, including evenings, weekends and holidays when the PD clinic is closed.
- A. Written instructions on how to access the system are provided to the patient and family members at the beginning of home dialysis training.
 - B. Instructions on accessing the system are reviewed at least annually with patient and family.
- D. Facility schedules patient appointments at the clinic at a mutually agreeable time when feasible for the following:
1. Initial PD home training.
 2. PD reinforcement or retraining.
 3. Clinic visits.
 4. PET testing.
 5. Medication administration.
- E. Facility informs patient and family members about their responsibility to comply with:
1. Dialysis treatment prescription (duration, frequency and dialysate).
 2. Clinic visits.
 3. Routine blood draws.
 4. Medication administration at home.
 5. Providing PD fluid samples to clinic, as instructed, for kinetics.

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- F. Facility identifies and tracks peritonitis episodes acquired while patient is under facility's care as an outpatient and those acquired during hospitalizations. Documentation includes start date of peritonitis episode, organism(s), new vs. relapsing episode, treatment(s) used and clinical outcome.

- G. Facility reinforces or retrains PD patient on aspects of training related to preventing peritonitis after each new episode of peritonitis.

- H. Facility has a formal, signed back-up agreement with local hemodialysis facility to ensure PD patients requiring short courses of back-up hemodialysis therapy (i.e., catheter leaks, peritoneal leaks, catheter removal for unresolved peritonitis) have access to this care. Whenever possible, back-up hemodialysis facilities should be selected based on proximity to patient's residence.

- I. Facility provides the following environmental safety measures for staff and patients:
 - 1. Conducts fire drills at least every six months with staff.
 - 2. Discusses facility evacuation plan with patient and family members at the beginning of PD home training.
 - 3. Instructs patient and family members on fire safety procedures to be followed at home, emphasizing patient and family safety.
 - 4. Patients should be instructed not to "rescue" dialysis equipment and supplies.
 - 5. Assists patient and family members to develop home disaster plan for "emergencies" (flood, hurricane, tornado, power outage, etc.).
 - 6. During PD home training, instructs all APD patients and family members on how to safely perform manual PD exchanges during an emergency:
 - a. Documents instruction on PD training record.
 - b. Reinforces instruction quarterly.

- J. Facility develops a policy for storage, preparation and administration of medications utilized in the PD home training area for demonstration or teaching purposes that includes:
 - 1. Administration of medications or supervision of medication administration by patient/family during training or clinic visits shall be the responsibility of licensed nurses, physician assistants or physicians.
 - 2. Easily accessible, clean, stable, well-lighted surface for preparation of medications will be provided.

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3. Multi-dose vials taken into the PD home training area are to be labeled with that PD patient's name, dedicated to that patient's use and stored in a designated, secure location in the PD home training area.
 4. Instructions to patient and family member on temperature requirements for medication storage, if applicable.
 5. Documentation of training for home ESA administration and intraperitoneal drug administration shall be documented by the licensed PD training nurse.
- K. Medical director is responsible for adequate training and monitoring of PD patients' dialysis outcomes.
- L. At a minimum, each patient receiving PD home training in the facility shall be seen by a physician on the medical staff prior to completing PD training.
- M. Following PD home training, PD patients shall be seen by a physician at least every three months.
- N. Orders for PD treatments shall include PD modality (CAPD, CCPD, NIPD), prescribed dialysate, frequency, duration, fill volumes, dwell times. (Also, if applicable for cycler – last bag fill and daytime fill volumes; for CAPD – fill volume of nighttime exchange with exchange device.
- O. PD clinical record shall include:
1. Documentation of each peritoneal dialysis home training session.
 2. Peritoneal dialysis home training checklist with competency of patient and/or family member noted for each skill.
 3. PD home contract signed by patient (or family member) that acknowledges dialysis-related responsibilities assumed by the patient or family member.
 4. Home dialysis treatment records provided by the patient.
 5. Documentation of re-training sessions.
 6. Clinic visit records, to include:
 - a. Patient assessment.
 - b. Review of current prescription, including PD modality, prescribed dialysate, frequency, duration, fill volumes and dwell times.
 - c. Discussion of patient's ability to adhere to current prescription.

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- d. Changes to current prescription, including PD modality, prescribed dialysate, frequency, duration, fill volumes and dwell times.
 - e. Review of patient's medications.
 - f. Procedures performed.
 - g. Documentation of educational reinforcement, if performed.
 - h. Documentation of nutritional assessment, education and, at a minimum, at least quarterly follow-up. (Evidence of nutritional problem evaluation and follow-up should be documented more often as needed.)
 - i. Documentation of social work assessment, education and, at a minimum, at least quarterly follow-up. (Evidence of psycho-social problem evaluation and follow-up should be documented more often as needed.)
- P. Facility develops a policy for training and follow-up visits for PD patients in nursing homes or long term acute care hospitals (LTAC) that addresses:
- 1. Initial PD training and retraining of nursing home or LTAC staff.
 - 2. Communication mechanism that promotes continuity of dialysis care for the patient.
 - 3. Nursing home or LTAC responsibilities following training:
 - a. Following and documenting dialysis prescription.
 - b. Trouble-shooting dialysis problems.
 - c. Ordering and storing dialysis supplies.
 - d. Transporting patient for clinic visits.
 - e. PET testing.
 - f. Dietary requirements.
 - 4. Accommodations for patients who are too ill or debilitated to be transported to the facility for clinic visits.
 - 5. Frequency of off-site clinic visit to nursing home/LTAC by PD nurse, social worker, dietitian and physician.

Standard VI: Facility Staffing, Training Curricula and Evaluation of Staff Competency

Facility provides safe, effective and timely PD care and services through the use of a staff-patient ratio that takes into account: 1) The finding that high-risk patients (elderly, diabetics and multiple co-morbidities) require 2-3 hours of nursing time per patient per week; and 2) The training, clinical, clerical, receptionist and quality management functions performed by the PD nurse at that facility and, if applicable, at other clinics for which the PD nurse has responsibilities.

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Measurement Criteria

- A. Facility staffing records indicate that, in addition to the licensed PD nurse, at least one other clinic staff member is on-site during clinic and patient treatment hours to assist in handling unscheduled patient visits and/or emergencies.

- B. Facility makes arrangements to provide trained, PD nurse back-up coverage if facility's regularly employed PD nurse is unavailable due to vacation or illness through PD cross training, direct hiring or utilization of a PD nurse employed by an affiliate facility.

- C. Facility staffs at a nurse to patient ratio of 1 licensed PD nurse for every 20 patients, or portion thereof, in addition to an on-site support staff person that assists in answering phones, filing lab data/reports, etc.

- D. Maximum staff-patient ratio does not exceed 1 licensed PD nurse for every 25 patients.

- E. The licensed nurse initiating PD home training is an RN.

- F. The licensed vocational nurse (LVN) functions in the PD facility under the direct supervision of an RN. An RN is accessible to patients during training at all times and home training documents are co-signed by an RN.

- G. The licensed vocational nurse (LVN) with two years of peritoneal dialysis and home training experience, who has demonstrated competency through national certification or completion of a facility based training program may expand his (her) scope of practice, provided written protocols for the expanded scope of practice are approved by the Medical Director. In this case, the expanded scope of practice for the LVN would include tasks routinely performed by the RN, including:
 - 1. Patient assessment – vital signs and data.
 - 2. Initiation and termination of PD procedures.
 - 3. Sterile dressing changes, tubing changes and catheter flushes.
 - 4. Modality choices education for CKD patients.
 - 5. Assist with PD home training under the direct supervision of an RN.
 - 6. Conduct re-training as directed.
 - 7. Conduct home visits as directed.
 - 8. Preparation, administration and recording of medications in accordance with the P&P of the facility and state nursing regulations.

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9. Communicate with other healthcare team members regarding patients' physical and mental condition and immediate notification to RN or physician of significant changes in patients' condition.
10. Coordination of laboratory tests, including venipuncture for lab tests, processing specimens and timely follow-up of abnormal lab tests.
11. Performing kinetics, PET and assisting in kinetic modeling.
12. Monitoring infectious and non-infectious complications, implementing peritonitis protocol.
13. Maintenance of patient medical records.
14. Assisting in facility inventory and supply issues.
15. Participation in CQI process.

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Non-Applicable or Revised DSHS ESRD Licensure Rule References For Outpatient Peritoneal Dialysis Facilities	ESRD Licensure Reference Codes*
1. HD Water Treatment System, Reuse, Reprocessing Language	117.11e (2B-D) 117.11f(2B) 117.31a (4-5) 117.33a-d 117.41g (4A, 4C) 117.43a (9, 11) 117.44f (1) 117.44f (2-5) 117.44f (4)
2. Square Feet Requirement for HD stations	117.31a (7)
3. Requirement for separate or "isolation" room for HBsAg+ patients	117.31a (8, 17)
4. Back-up dialysis machine	117.32c
5. Routine disinfection of active/backup dialysis machines	117.33b (2A) 117.34b (2A)
6. Hepatitis B Prevention and Procedures for HbsAg+ PD patients	117.34d (2Bi, Biil) 117.34d (2C) 117.34d (2C, i-v)
7. Tuberculosis Prevention	117.34e (2A)
8. Technical supervisor references	117.41f
9. Charge nurse references and requirements	Entire document
10. Administration of NS, SQ Lidocaine and O ₂ by Technician	117.43c (9)
11. HD treatment and provision of required services for hemodialysis.	117.43j (2E, i-ii) 117.43k (3A)
12. Medication Storage and Administration	117.43d (6,7,9)
13. Provision of Services – Staff Related	117.43e (4-6, 7A,B) 117.43g 117.43h (3,6) 117.43i (3,6)
14. Patient education reference	117.45a (7P)
15. Daily treatment record references	117.45a (7P) 117.45d
16. Qualifications of Staff	117.44 f
17. Staff Training Curriculum, competency and prohibited acts for dialysis technicians, including references to reuse, water systems, HD, access cannulation, administration of saline, heparin or lidocaine, HD, dialysate preparation, reprocessing, line separation, hemolysis, dialyzers	117.62b (2B-C), 117.62b (4F),(5A) 117.62b (6) 117.62c (2A-E) 117.62g (4) 117.63c,e (1-4), f 117.65b (2-8)