



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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COMMISSIONER

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December 7, 2010

The following Chapter 117 ESRD Rule Clarifications apply to the rules effective July 6, 2010, which remain in full effect. These clarifications will assist surveyors and facilities with interpreting and understanding the intent and application of the rules during the state survey process.

1) History & Physical:

Section 117.45(a)(7) The facility shall monitor the plan of care at least monthly to recognize and address any deviations from the plan of care as follows:

- (A) implement changes in interventions due to the lack of progress toward the goals of the plan of care;
- (B) document as to the reasons why the patient was unable to achieve the goals; and
- (C) implement changes to address the revised plan of care.

Clarification

The facility will need to ensure that the physicians complete the history and physical as outlined in the facility's policies and procedures.

The social worker and the patient's plan of care:

The social worker has goals and tasks to accomplish to ensure that their interventions were appropriate, and to ensure, based on their expertise, that the patient is stable regarding their psychosocial status. Per the Federal regulation, a patient is unstable if there is a change in their psychosocial status. Therefore the social worker needs to ensure that the patient is stable regarding their psychosocial status.

The individual dialysis facility determines how this is accomplished. The complete chart is considered the plan of care. The surveyor will review progress notes, physician's orders, etc., to ensure that the plan of care is monitored at least monthly.

2) Charge nurse qualifications:

Section 117.46 (c) (1) Each person licensed as a nurse shall have a current Texas license to practice nursing in accordance with the statutes and rules of the Texas Board of Nursing.

(2) Each registered nurse assigned charge nurse responsibilities shall have at least 12 months of clinical experience and have six months experience in hemodialysis subsequent to completion of

12/17/2010

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the facility's training program. The hemodialysis experience shall be within the last 24 months. A registered nurse who holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis may substitute the certification for the six months experience in dialysis obtained within the last 24 months.

Clarification

To be charge nurse in a licensed Texas dialysis facility, the RN must be currently licensed in Texas and have at least one year of clinical experience and six months of dialysis experience. For a newly licensed RN, the last six months of clinical experience may run concurrently with the six months of dialysis experience.

3) Clinical sink:

Section 117.102(d)(11)(B)

(B) An additional clinical sink or equivalent flushing rim sink with hands-free operable controls shall be provided. The clinical sink or equivalent flushing rim sink and the hand washing sink shall have a minimum separation of 6 feet.

Clarification

In lieu of a clinical sink or equivalent flushing rim sink, a deep sink may be substituted. The deep sink shall be a minimum of 12 inches deep. These sinks are classified as the dirty sink and shall be located in isolation rooms, treatment areas/rooms, and peritoneal dialysis training rooms. This clarification of the clinical sink applies to all references of a clinical sink in the rules.

4) Water:

Section 117.32(b)(8)(C)(iv) - A sample port shall also be installed following the second bed for use in the event of free chlorine or chloramine breaking through the first bed. Water from this port(s) shall be tested for chlorine/chloramine levels at the beginning of each treatment day prior to patients initiating treatment, prior to reprocessing of dialyzers, and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed every four hours during hours of operation.

Clarification

Water from a sample port following the first bed shall be tested for chlorine/chloramine levels at the beginning of each treatment day prior to patients initiating treatment, prior to reprocessing of dialyzers, and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed every four hours during hours of operation.

5) Definitions:

Section 117.2 (50) (50) Modality--Different treatment options and settings for patients with end stage renal disease, for example, in-center dialysis, home hemodialysis, peritoneal dialysis, self-care dialysis, nocturnal dialysis, and transplantation.

Clarification:

Modality--Different treatment options for patients with end stage renal disease, hemodialysis, and peritoneal dialysis.

6) Incident Reports – please see reporting clarifications on the attachment.

**INSTRUCTIONS FOR COMPLETING ESRD FACILITY INCIDENT REPORT
TEXAS DEPARTMENT OF STATE HEALTH SERVICES (DSHS)
REGULATORY LICENSING UNIT - FACILITY LICENSING GROUP**

Use this form to notify DSHS of an incident and the actions taken by the facility. Explain how the facility will improve care as a result of the incident. Complete the entire form with all requested attachments so that the DSHS may review the incident without requiring additional information or documents.

Instructions for Completing the Incident Report

Print or type the information. Provide as much information as possible. Use the facility name and license # on your license.

Reporting Information: Incident reports are required for the following:

1. death of a patient (**Do not report death related to a traffic accident, pre-scheduled elective surgery, hospitalization greater than 14 days, a do-not-resuscitate (DNR) directive, a hospice patient, or a patient who withdraws from dialysis**);
2. any ambulance transport from the dialysis facility to a hospital due to the patient's emergent medical condition; this includes ambulance transports after a call to 911, whether or not the lights are flashing and or the siren is on as the ambulance leaves the dialysis facility or parking lot; **do not report non-emergent transports**.
3. conversion of staff or patient to hepatitis B surface antigen (HbsAg) positive (Submit a report with lab results for all patients and staff in the facility, with their hepatitis status, antibody status, and vaccination status);
4. involuntary transfer or involuntary discharge of a patient;
5. fire in the facility (Submit the report from the fire department.).

Facility Information: Include the facility license number, facility provider number, address, contact person, telephone number, email address, and fax number. The facility license number is on your facility license. The facility provider number is the Medicare six digit number. The contact person will be the person the surveyor will ask for should a follow-up telephone call be needed.

Summary: Briefly state what happened, who was involved (e.g., RN, LVN, PCT, MD, other), and what action was taken at the time of the incident. For example: The treatment was started without incident. About 2 Y, hours after the treatment began, the PCT noted that the patient's blood pressure dropped from 130 systolic to 90 systolic. The nurse assessed the patient and found the patient was asymptomatic. The blood pressure was retaken, and it was 92 systolic. The patient was placed in Trendelenburg position, and the blood pressure was retaken after 15 minutes. The patient began experiencing dizziness, and the blood pressure was now 89 systolic. The nurse administered 200 cc normal saline. After 15 minutes the blood pressure dropped to 80 systolic, and the physician was notified. 911 was called and the patient was transferred to the hospital for evaluation. She remained there overnight and was discharged within 48 hours.

Narrative: Provide a narrative report of your investigation. Explain how you handled the incident and what actions you will take to reduce the potential for similar incidents in the future. For example: The investigation concluded: The patient's record was evaluated, and it was noted that the patient had been experiencing hypotension (down to 95 systolic) for the past 2 weeks during the dialysis treatment. The dietitian had identified about 3 weeks ago that the patient had gained weight following the Christmas holidays. The physician had not adjusted the patient's dry weight. An interdisciplinary team met to discuss the change in the patient's condition. The dry weight was increased by 3 kgs and a plan was discussed to assist the patient in weight loss. A representative of the interdisciplinary team met with the patient after her return to the clinic to discuss the change in the patient care plan. The patient agreed with the dietary plan and will meet with the dietitian bi-monthly to evaluate her progress. The patient's fluid status will be evaluated monthly or as required according to the dietitian's report. Staffing on 091010 met state requirements. The registered nurse assessed and documented the assessment at the time of the incident. QA discussed failure of staff to identify and report the patient's hypotension for 2 weeks. Educated staff and physicians. This QA indicator will be completed ongoing on a monthly basis.

Treatment Information: Check the services type (HD In-Center, PD, or Home HD). Also check the access type (graft, fistula, central catheter, or PD). Please complete the charts based on the example below. Please attach copies of the last 3 treatment sheets. If the patient is deceased, also include the mortality review of the patient.

| Date | Pulse | | Blood Pressure | | Weight | |
|------|-------|------|----------------|--------|--------|------|
| | Pre | Post | Pre | Post | Pre | Post |
| 2/14 | 80 | 74 | 130/74 | 120/65 | 84kg | 80kg |

| Hct. or Hgb. | | Kt/V or URR | | Potassium | |
|--------------|--------|-------------|--------|-----------|--------|
| Date | Result | Date | Result | Date | Result |
| 2/9 | 33.1 | 2/1 | 67% | 2/1 | 4.5 |

Patient Transfer: If the patient is transferred to another facility, please include the name of the facility and the date of transfer. In addition to the above information, please include the following: Plan of care and reassessment of the patient's plan of care; evidence of interventions with the patient and/or care-giver (i.e. progress notes); coordination with Network 14; physician's orders; copies of letters to patients; and copies of policies/procedures for involuntary transfer of a patient.

Signature: The supervising nurse must print name and title, sign, and date the incident report. Fax or mail the completed incident report to the number or address provided. Do not put any information in the box marked "DSHS Use Only."

Thank you for your cooperation. For questions, please call (512) 834-6646 or your Health Facility Compliance (HFC) Zone Office The link to the DSHS Zone Map and HFC Zone contact information is below:
<http://www.dshs.state.tx.us/hfp/default.shtm>

DSHS Use Only
Complaint Number:

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT – FACILITY LICENSING GROUP
INCIDENT REPORT**

Reporting Information

Reportable Incident:

- | | |
|---|---|
| <input type="checkbox"/> Death of a Patient | <input type="checkbox"/> Hospital Transfer |
| <input type="checkbox"/> Hepatitis B Conversion – Patient | <input type="checkbox"/> Hepatitis B Conversion - Staff |
| <input type="checkbox"/> Involuntary Transfer or Discharge of a Patient | <input type="checkbox"/> Fire in the Facility |

Date of this report: ____/____/____ Date of the incident: ____/____/____ Time of the incident: ____am/pm

Date of last dialysis treatment: ____/____/____

Facility Information

Facility License #: _____ Facility Provider # _____
Name of Facility: _____
Address: _____ City: _____ Zip: _____
Contact Person: _____ Telephone: _____
Email: _____ Fax Number: _____

Summary

Provide a brief summary of the incident (what happened, who was involved, what action was taken at the time of the incident) (Please attach a separate sheet if necessary.)

Narrative

Provide a narrative report of your investigation (how was the incident handled, what actions will be taken to reduce the potential of similar incidents in the future) (Please attach a separate sheet if necessary.)

Action

Action you will take as a result of this incident: (check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Education of staff | <input type="checkbox"/> Corrective action and monitoring |
| <input type="checkbox"/> Education of patient | <input type="checkbox"/> Revision of policy/procedure |
| <input type="checkbox"/> Education of care-giver | <input type="checkbox"/> Development of policy/procedure |
| <input type="checkbox"/> Measure, analyze, and track in QAPI (Quality Assessment and Performance Improvement) | |
| <input type="checkbox"/> Information is incomplete at this time. A follow-up narrative will be sent within 30 days | |
| <input type="checkbox"/> Other: _____ | |

Patient Information

If the incident involves a patient, please complete the following:

Patient's First Name: _____ Middle: _____ Last: _____
DOB: / / Started dialysis: / / Admitted here: / /
Diagnoses (all): _____

Current Condition: *(check one)*

- Return to previous modality at this facility
 In Hospital _____ *(name of hospital)*
 Deceased

Treatment Information

Service Type: *(check one)*

- HD In-Center
 PD
 Home HD

Access Type: *(check one)*

- Graft Fistula
 Central Catheter PD

Current Dry Weight: _____ Kg Total Heparin Dose: _____ Units Reuse #: _____

Complete the following charts for the treatment involved, the last two treatments, and the most recent labs. Please attach copies of the last 3 treatment sheets. If the patient is deceased, also include the mortality review of the patient.

| Date | Pulse | | Blood Pressure | | Weight | |
|------|-------|------|----------------|------|--------|------|
| | Pre | Post | Pre | Post | Pre | Post |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| Date | Hct. or Hgb. Result | Date | Kt/V or URR Result | Potassium | |
|------|---------------------|------|--------------------|-----------|--------|
| | | | | Date | Result |
| | | | | | |
| | | | | | |
| | | | | | |

Patient Transfer

Complete this section only if the patient was transferred to another facility.

Name of Facility: _____ Date of Transfer: _____

In addition to the above information, please include the following: plan of care and reassessment of the patient's plan of care; evidence of interventions with the patient and/or care-giver (i.e. progress notes); coordination with Network 14; physician's orders; copies of letters to patient; and copies of policies/procedures for involuntary transfer of a patient.

Signature: _____ Date: _____

Printed Name: _____ Title: _____

Forward within ten working days of incident to:

**Texas Department of State
Health Services
Regulatory Licensing Unit
Facility Licensing Group
Delivery Code 2835
PO Box 149347
Austin, TX 78714-9347
FAX: 512-834-4514**

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Reviewed by: _____ Date: _____
__No Action required __Action required:

