

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012501	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Gadsden Dialysis	Street Address, City, State 409 South First Street, Gadsden, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies (Each deficiency should be preceded by full regulatory or LSC identifying information)
E0000	A recertification survey was conducted for in-center hemodialysis, Gadsden Dialysis was found to be in compliance with the Conditions of Participation for Emergency Preparedness.
V0000	"CORE" A re-certification survey was conducted on 3/14/19 at Gdsden Dialysis. Standard Level deficiencies were cited.
V0143	<p>IC-ASEPTIC TECHNIQUES FOR IV MEDS CFR(s): 494.30(b)(2)</p> <p>[The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>This STANDARD is not met as evidenced by: Based on review of facility policy, observations, ABN (Alabama Board of Nursing) Standards of Nursing Practice, and interviews, it was determined the facility failed to ensure: 1) The RN (Registered Nurse) delegated tasks according to non-licensed staff scope of practice. 2) The RN stored, administered, and controlled all medications. 3) All open multidose medication vials were labeled. 4) Expired supplies and medications were discarded by the facility staff. This affected Patient Identifier (PI) # 5 and had the potential to affect all patients treated at the facility. **** Findings include: Facility Policy: Medication Policy Policy #: 1-06-01 Revision Date: June 2017 "Purpose: To provide guidance for medication management in the facility and to provide guidance for the safe and aseptic preparation of all medications. Policy: 1. The Administrator/designee is responsible for supervising, storing, administering, and controlling of medications and performs a monthly audit and inventory ... 7. Heparin, Lidocaine, and normal saline may be drawn up and administered by licensed nurse teammates and patient care technicians, if allowable by their state and they have met</p>

their state's educational requirements ... 11. ...Non-refrigerated medications are to be stored in cabinet(s) and locked at the close of each business day or if not under supervision by the licensed teammate... 13. ...Do not use any ampule or vial that has been stored improperly or has expired... 22. Medications and needle/syringe storage are done in accordance with state regulations... 28. Medications containing a preservative must be discarded 28 days after opening or accessed (e.g., needle punctured), unless the manufacturer specifies a different (shorter or longer) date or as directed by the manufacturer as in the case of vaccines or state specific pharmacy regulations. Each vial is labeled with the initials of the person opening the vial and the expiration date... 29. All medications in the facility are checked monthly. Insulin and other medications with preservatives are dated and initialed once opened. All medications are checked monthly for expiration dates... 31. Disposal of expired medications, including all over the counter and nutritional product samples are removed from the treatment and inventory areas and disposed of per state/local regulations." ***** ABN (Alabama Board of Nursing) Chapter 610-X-6 Standards of Nursing Practice 610-X-6-.11 Assignment, Delegation And Supervision... 1. The registered nurse shall be accountable and responsible for the assignment of nursing activities and tasks to other health care workers based on, but not limited to: ...2. Assignments may not exceed the scope of an individual licensed nurse's scope of practice... 4. Tasks delegated to unlicensed assistive personnel may not include tasks that require: a. The exercise of independent nursing judgment or intervention. b. Invasive or sterile procedures. c. Assistance with medications... ***** 1. A tour of the treatment area and medication room was conducted on 3/12/19 at 9:15 AM by the surveyor. In the medication refrigerator, the surveyor observed the following: Tubersol, 10 test, 5 ml (Milliliter) opened vial. There was no label on the vial for the date opened, initials of the person who opened the vial and the date to be discarded. Humulin R (regular insulin) 10 ml vial with an opened date documented as 11/20/17. In the emergency cart, the surveyor observed the following: Normal Saline 0.9 % (percent) sodium chloride 1000 ml bag with an expiration date of 8/2018 - (24 bags) The surveyor observed Purell Instant Hand Sanitizer 354 ml bottle with an expiration date of 5/2018 located on the counter of the clean sink in the medication room. An interview was conducted on 3/14/19 at 10:30 AM with Employee Identifier (EI) # 1, Group Facility Administrator who confirmed the above findings. 2. During an observation of care on 3/13/19 at 10:23 AM, the surveyor observed EI # 4, RN, place the following medications on PI # 5 hemodialysis chairside table: 2 syringes filled with Hecetrol totaling 4.5 mg (milligrams), and 1 syringe filled with Erythropoietin 10,000 units. EI # 4 walked away from the medications and returned at 10:54 AM to administer the medications. Further observation revealed EI # 5, Certified Clinical Hemodialysis Technician connected PI # 5's heparin syringe to the patient's venous needle line. EI # 4 returned to the patient's chairside and administered the heparin. EI # 5, assisted in the administration of heparin by removing the needle and cap from the heparin syringe and connecting the heparin to the patient's venous needle line. EI # 4 left the heparin unattended. EI # 4 failed to store medications as directed per facility policy. An interview was conducted on 3/14/19 at 10:30 AM with EI # 1, who confirmed the above findings.

V0504

PA-ASSESS B/P, FLUID MANAGEMENT NEEDS
CFR(s): 494.80(a)(2)

The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs.

This STANDARD is not met as evidenced by:

Based on review of the facility's policies and procedures, medical records and interviews with staff, it was determined the agency failed to: 1) Document reasons for not meeting the physician's order on patient's estimated dry weight (EDW) post dialysis treatment. 2) Follow the physician's standing orders for Blood Pressure (BP) parameters. 3) Follow the physician's order for Blood Flow Rate (BFR) and Dialysate Flow Rate (DFR). 4) Document vital signs every 30 minutes according to facility policy. This deficient practice affected 3 of 5 records reviewed including Patient Identifier (PI) # 1, # 3, # 4, and had the potential to negatively affect all patients served by the facility. Findings include: Title: Pre- Intra- Post Treatment Data Collection, Monitoring and Nursing Assessment Policy No: 1-03-08 Revision Date: April 2017 Purpose: To obtain and document baseline and ongoing information about the patient before, during and after the dialysis treatment through data collection and nursing assessment. This information will be used in planning and documenting the patient's dialysis treatment, monitoring during treatment and for reviewing the patient's response to the treatment and status prior to discharge. 12. The licensed nurse notifies the physician (or AHP (allied health professional) as needed for changes in patient status. 1. PI # 1 was admitted in dialysis on 6/5/18 with the diagnoses including Anemia In Chronic Kidney Disease and End Stage Renal Disease. Review of the the Kardex/ Hemodialysis Treatment Orders dated 1/15/19 revealed the BFR (Blood Flow Rate) was at 400. Review of the Hemodialysis Treatment Sheet dated 2/25/19 revealed the BFR was reduced to 350 at 11:37 AM, then reduced to 200 at 2:30 PM . There was no documented reason for the decrease in the BFR. Review of the Hemodialysis Treatment Sheet dated 2/27/19 revealed the BFR was reduced to 350 at 11:31 AM, then to 300 from 12:01 PM to 3:54. There was no documented reason for the decrease in the BFR. Review of the Hemodialysis Treatment Sheet dated 3/1/19 revealed the BFR was reduced to 250 from 12:05 PM to 1:13. There was no documented reason for the decrease in the BFR. Review of the Hemodialysis Treatment Sheet dated 3/8/19 revealed the BFR was reduced to 350 from 10:59 AM to 2:02 PM. There was no documented reason for the decrease in the BFR. An interview was conducted on 3/14/19 at 9:30 AM with Employee Identifier (EI) # 1, Group Facility Administrator (GFA) who confirmed the staff failed to follow the physician's orders. 2. PI # 3 was admitted to dialysis on 7/4/18 with a primary diagnosis of End Stage Renal Disease. Review of the Hemodialysis Treatment Sheet dated 1/2/19 revealed BFR was ordered at 400 according to the physician's orders. Review of the Treatment Sheet dated 2/25/19 revealed the BFR was lowered to 300 at 10:30 AM until the end of treatment at 12:27 PM. There was no documentation of the reason BFR was not administered as ordered. Review of the Treatment Sheet dated 3/4/19 revealed the BFR was lowered to 350 from 10:13 AM until the end of treatment at 1:00 PM. The staff failed to ensure documentation was provided as to the reason the BFR was lowered. An interview was conducted on 3/14/19 at 9:45 AM with EI # 1, who confirmed the above mentioned findings. 3. PI # 4 was admitted to dialysis on 12/22/18 with a primary diagnosis of End Stage Renal disease. Review of the PRN (As Needed) Orders dated 12/23/18 revealed to administer Clonidine 0.20 mg. (milligram) by mouth 0.2 mg for systolic blood pressure (BP) greater (>) than 200. May repeat in 1 hour if systolic BP still > 200. Call physician (MD) if BP still >200 systolic after 2nd dose. Review of the Treatment Sheet dated 12/31/18 revealed BP was 206/132 at 1:01 PM and at 1:31 PM BP was 202/141. There was no documentation the anti hypertensive medications Clonidine was administered. An interview was conducted with EI # 1 at 9:40 AM on 3/14/19 who confirmed the aforementioned findings.

V0516

PA-FREQUENCY-INITIAL-30 DAYS/13 TX
CFR(s): 494.80(b)(1)

An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.

This STANDARD is not met as evidenced by:

Based on the review of the facility policy, medical records (MR), and interviews with the staff, it was determined the facility failed to ensure the patients Initial Plan of Care was completed within 30 calendar days or 13 treatments of admission for 1 of 1 newly admitted patient to the facility. This affected Patient Identifier (PI) # 2, and had the potential to affect all new patients served by this facility. Findings include: Title: Interdisciplinary Teams (IDT) Patient Assessment and Plan of Care (POC) Policy number: 1-14-01 Revise date: October 2018 Purpose: To provide guidance for the development of patient assessment and plan of care for IDT (Interdisciplinary Team) teammates. Policy: Assessment: ... A comprehensive assessment will be conducted on all new patients within 30 calendar days (or 13 outpatient dialysis sessions for hemodialysis) beginning with the first outpatient dialysis treatment or per state guidelines... ... Plan of Care: 8. The facility's interdisciplinary team will develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs... 10. An initial Plan of Care, based on the findings from the comprehensive assessment, will be completed on all patients new to dialysis within 30 calendar days (or 13 outpatient dialysis sessions for hemodialysis) beginning with the first outpatient dialysis treatment or per state guidelines... 14. The patient's plan of car will be completed by the facility's interdisciplinary team, including patient or personal representative and be signed by the team members including the patient or the patient's personal representative..."

***** 1. PI # 2 was admitted to dialysis on 12/7/18 with a primary diagnosis of End Stage Renal Disease. Review of the Initial Interdisciplinary Care Plan meeting revealed it was dated 12/3/19 (future date) and was signed by the Physician, Nurse, Dietitian, Social Worker, and PI # 2. There was no way to determine if PI # 2's POC was completed within 30 calendar days or 13 outpatient dialysis treatments because of the 12/3/19 future date documented. The IDT failed to complete PI # 2's POC per facility policy. An interview was conducted on 3/14/19 at 10:04 AM with Employee Identifier # 1, Group Facility Administrator, who confirmed the above findings.

V0520

PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO
CFR(s): 494.80(d)(2)

In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted- At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.

This STANDARD is not met as evidenced by:

Based on review of medical records (MR), facility policy, and interview with the staff it was determined the agency failed to ensure the Interdisciplinary Team completed monthly care plans for all unstable patients. This affected patient identifier (PI) # 5, 1 of 3 unstable in-center hemodialysis MRs reviewed and had the potential to negatively affect all in-center hemodialysis patients served by the facility. Findings include:

Policy: Interdisciplinary Teams (IDT) Patient Assessment and Plan of Care (POC)
 Policy Number: 1-14-01 Revision Date: October 2018 "Assessment: 1. The facility's IDT consists of, at a minimum, the patient or the patient's personal representative, a registered nurse, a physician or allied health professional, if allowed by state End Stage Renal Disease (ESRD) licensure regulations, treating the patient for ESRD, a social worker, and a dietitian. 2. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment documenting his/her needs. The comprehensive assessment will be used to develop the patient's treatment plan and expectations for care... 7. A comprehensive re-assessment of each patient and revision in the plan of care will be conducted: ... At least monthly for unstable patients including, but not limited to, patients with the following: Extended or frequent hospitalizations, marked deterioration in health status, significant changes in psychosocial needs, concurrent poor nutritional status, and unmanaged anemia and inadequate dialysis... Plan of Care ... 12. Subsequent interdisciplinary re-assessments should be completed within the 30 days following the initiation of the re-assessments. The Plan of Care following re-assessments must be completed within 15 days of completing the re-assessment. This process would occur monthly for unstable patients and annually for stable patients... 14. The patient's plan of care will be completed by facility's interdisciplinary team, including patient or personal representative..." 1. PI # 5 was admitted to the facility on 5/9/18 with a diagnosis of ESRD. Review of MR on 3/13/19 revealed documentation that PI # 5 was deemed unstable on 9/24/18. Further review of the MR revealed there was no documented unstable POC for 10/2018 and the next POC was completed on 11/7/18. The IDT failed to document an unstable POC monthly per facility's policy. An interview was conducted on 3/14/19 at 10:00 AM with Employee Identifier # 1, Group Facility Administrator, who verified the above findings.

V0544

POC-ACHIEVE ADEQUATE CLEARANCE
 CFR(s): 494.90(a)(1)

Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

This STANDARD is not met as evidenced by:
 Based on observation, review of medical records (MR), facility policies and interviews, it was determined the facility failed to ensure patient signs an AMA (Against Medical Advice) form when unable to complete treatment and treatment time as ordered by the physician. This deficient practice affected 3 of 5 MR reviewed including Patient Identifier (PI) # 4, # 5, # 2, and had the potential to negatively affect all patients served by the facility. Findings include: Title: Shortened/ Early Termination Of Treatment Or Extended Treatment Policy No: 1-01-09 Revision Date: October 2017 Purpose: To provide requirements for teammates to follow when a patient's treatment is terminated early or extended. Policy: 1. The RN (registered Nurse) verify that a patient signs and Early Termination of Treatment Against Medical Advice for any time the patient requests to terminate their treatment earlier than the prescribed run time. 3. The RN will obtain the patient's signature on the Early Termination of Treatment Against Medical Advice form prior to the patient being rinsed back from their treatment. ... 4. A RN must countersign the Early Termination of Treatment Against Medical Advice form. ... B. Shortened/ early Termination Of Treatment 3. If a patient's treatment is shortened/ early terminated, the RN will document the event in the patient's medical record. Documentation will include, as

appropriate: The amount of time of which the treatment was shortened. A description of why the treatment was shortened. A copy of the early Termination of Treatment Against Medical Advice form signed by the patient, ...

1. PI # 4 was admitted to dialysis on 12/22/18 with a primary diagnosis of End Stage Renal Disease. Review of the Hemodialysis Treatment Orders 12/23/18 revealed patient's treatment time was 240 minutes. Review of the Treatment sheet dated 1/30/19 ended at 221 minutes, a difference of 19 minute from the ordered treatment time. The staff failed to obtain a signed Against Medical Advice (AMA) form from the patient. An interview was conducted 03/14/19 at 9:40AM with EI # 1, Group Facility Administrator, who confirmed the above mentioned findings. 37268
2. PI # 5 was admitted to dialysis on 5/9/18 with a primary diagnosis of ESRD. Review of the Hemodialysis Prescription Information dated 2/22/19 revealed documentation the ordered treatment time was 240 minutes. Review of the Post Treatment Sheet 2/22/19 revealed documentation of the treatment time was 187 minutes, 53 minutes less than the ordered treatment time. There was no documentation of an AMA. An interview was conducted on 3/14/19 at 10:00 AM with EI # 1, who confirmed the above mentioned findings.
3. PI # 2 was admitted to dialysis on 12/7/18 with a primary diagnosis of ESRD. Review of the Hemodialysis Prescription Information dated 2/27/19 revealed documentation the ordered treatment time was 240 minutes. Review of the Post Treatment Sheet 2/27/19 revealed documentation of the treatment time was 213 minutes, 27 minutes less than the ordered treatment time. There was no documentation of an AMA. An interview was conducted on 3/14/19 at 10:00 AM with EI # 1, who confirmed the above mentioned findings.