

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012306	(X3) Date Survey Completed 06/24/2021
Name of Provider or Supplier Childrens Hospital Of Alabama Esrd	Street Address, City, State 1600 7th Avenue South, Birmingham, 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	Based on a recertification survey conducted on 6/22/21 to 6/24/21, The Children's Hospital of Alabama ESRD was found to be in substantial compliance with the Condition of Participation for Emergency Preparedness.
V0000	[ESRD Core Survey]
V0113	<p>IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1)</p> <p>Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>This STANDARD is not met as evidenced by: Based on observations, review of facility procedure and interview, it was determined the facility failed to ensure staff followed their procedure for cannulation of AV (Arteriovenous) Graft/Fistula and perform hand hygiene after access site evaluation. This affected 1 of 2 patient observations for access site cannulation that included Patient Identifier (PI) # 8, and this had the potential to negatively affect all patient who dialyzed at this facility. Findings include: AV (arteriovenous) Fistula-Assessment, Cannulation, De-cannulation and Lab Draw Departmental Procedure No. 18335 Last Revised/Reviewed: 1/29/2020 I. Purpose The purpose of this procedure is to provide guidelines for routine AV Fistula/Graft cannulation, decannulation, and assessment of the AV Fistula/Graft. VI. Procedure E. Cannulation of a New AV Fistula/Graft (AVG) 2. Procedure d. Assess the Fistula/Graft i. Determine the directional flow ii. Check the bruit and thrill... f. Wash hands. Apply gloves. g. Prep site... i. Cannulate at a 25 degree angle... An observation of care on 6/23/21 at 9:05 AM for treatment initiation using an AVG with EI (Employee Identifier) # 4, RN (Registered Nurse) was conducted. At station 2, EI # 4 evaluated the AVG site, first</p>

by palpation with gloved hands, and then with a stethoscope. EI # 4 applied alcohol wipes to the AVG access site of PI # 8, an unsampled patient, then cannulated the access site. EI # 4 failed to remove gloves and perform hand hygiene after AVG site evaluation and prior to cannulation. In an interview on 6/23/21 at 9:25 AM following the observation, EI # 2, RN, Charge Nurse, also present during the procedure, verified the observation and confirmed staff failed to follow the facility procedure and perform hand hygiene after access evaluation.

V0122

IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL
CFR(s): 494.30(a)(4)(ii)

[The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

This STANDARD is not met as evidenced by:
Based on observation, review of facility policy and procedure and interview, it was determined staff failed to follow its own procedure and disinfect all surfaces at the dialysis station. This affected 1 of 2 observations of cleaning the dialysis station and had the potential to affect all patients who dialyzed at the facility. Findings include: Department Policy No. 18640-Infection Control of Dialysis Equipment Department: Renal Care Center Last Revised/Reviewed: 11/20/19 I. Purpose ...to provide current infection prevention and control guidelines regarding cleaning and disinfecting... equipment...to prevent cross-contamination between patients and care-providers. VII. Procedure A. Each dialysis station is cleaned and disinfected prior to each patient's use...includes...not limited to...chair fully reclined, tables, TV...dialysis machine... During observations of cleaning/disinfection at station 7 on 6/22/21 at 3:55 PM, Employee Identifier (EI) # 8 , Unit Support Staff, failed to disinfect the Hansen dialysate hoses on the hemodialysis machine. EI # 8 failed to disinfect the treatment chair surface underneath the right side tabletop. In an interview on 6/24/21 at 11:00 AM, EI #1, Dialysis Coordinator confirmed both surfaces were to be disinfected after the station was vacated.

V0250

DIALYS PROPOR-T-MONITOR PH/CONDUCTIVITY
CFR(s): 494.40(a)

5.6 Dialysate proportioning: monitor pH/conductivity It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.

This STANDARD is not met as evidenced by:
Based on observations, review of the pHOenix XL User's Guide, facility procedure and interviews, it was determined the facility failed to ensure the staff rinsed the pHOenix meters with RO (reverse osmosis) water after use. This affected 2 of 2 observations for unsampled patients, Patient Identifier (PI) # 6 and PI # 7, and this had the potential to negatively affect all patients who dialyzed at this facility. Findings include: pHOenix XL User's Guide Pages: 15-17 F. Taking Measurements A. Sample Directly from the Hemodialysis delivery system: 1. Connect to Dialysis Machine ...6. Close the valve, disconnect from the dialysis system, and record the readings. 7. See

Final Steps on Page 17. Final steps: 1. Press the Menu button to deactivate the hold feature and begin normal measurements... 2. Rinse the sample cup/tube thoroughly with treated water when finished. Rinse the cell meter and syringe interior thoroughly with treated water prior to storage. Phoenix XL Meter Dialysate Testing Departmental Procedure No. 18372 Last Revised/Reviewed 03/08/19 V11. Procedure The conductivity and pH of Dialysate will be checked before every dialysate treatment... F. Once testing is complete; discard the used solution... G. The instrument will turn off automatically... H. Rinse the cell, syringe interior, and sampling cup/tube thoroughly with RO water after use. I. Keep cell filled with RO water during use. J. Pack with Neo-care....at the end of use... 1. An observation was conducted on 6/23/21 at 11:25 AM to observe Employee Identifier (EI) # 5, Registered Nurse (RN), prepare the dialysis machine for PI # 6 at station 8. EI # 5 performed conductivity and pH testing, and placed the meter on the counter. After testing was complete, EI # 5 failed to rinse the pHOenix meter thoroughly with dialysis quality water. 2. An observation was conducted on 6/23/21 at 11:45 AM to observe EI # 7, RN, perform conductivity and pH testing at station 5 prior to arrival of an unsampled patient, PI # 7. After testing was complete, EI # 7 failed to rinse the pHOenix meter thoroughly with RO water. An interview was conducted on 6/24/21 at 10:00 AM with EI # 6, Biomedical Supervisor, who verified the staff failed to follow the pHOenix XL User's Guide and facility procedure and rinse the pHOenix meter with RO water after each use.

V0403

PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU
CFR(s): 494.60(b)

The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

This STANDARD is not met as evidenced by:
Based on observations in the PD (peritoneal dialysis) exam/therapy rooms, review of the facility equipment visual/electrical safety inspection procedure and staff interviews, it was determined staff failed to complete PD cyclers inspections. This had the potential to negatively affect all PD patient served by the facility. Findings include: Procedure Detail Report Procedure #: 430 OVP60CLS-60 Day Verification of Rental Equipment in the Hospital Type: Preventative Maintenance (PM) Task Date-3/2/17 2) Do a visual inspection 3) Verify proper operation 4) Check with operator concerning proper operation 5) Verify safety of device and if applicable perform electrical safety On 6/22//21 at 2:00 PM, tour of the 2 PD exam/treatment/training rooms with EI (Employee Identifier) # 9, PD, Home Therapy RN (Registered Nurse) revealed in exam 1, a HomeChoice Pro PD cycler SN 71631 (serial number) with inspection documentation, due date 1/2021. EI # 9 reported this is a rental machine and PM (preventative maintenance) was overdue. Found in the Home Therapy Room was 1 Amia (automated PD system) PD Cycler with machine documentation, electrical safety check inspection due 5/2021. In an interview on 6/22/21 at 2:35 PM, EI # 9 confirmed the PD cyclers PM inspections were overdue and not current. During an interview on 6/24/21 at 10:00 AM, EI # 6, Biomedical Supervisor confirmed the PD cyclers PM had not completed as required.

V0586

H-PT/CAREGIVER DEMO COMPREHEND TRAINING
CFR(s): 494.100(b)(1)

The dialysis facility must - (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

This STANDARD is not met as evidenced by:

Based on medical record (MR) review, the facility PD (Peritoneal) Training Plan, policy and procedure and staff interview, it was determined the facility staff failed to ensure all home PD therapy patient/caregiver (cg) education and training was documented and included the successful return demonstration for Epogen administration. This affected Patient Identifier (PI) # 4 and PI # 5, 2 of 2 PD records reviewed and has the potential to affect all home therapy patients served. Findings include: Peritoneal Dialysis Training Plan Section: PD Written: 6/18 Purpose To provide guidance for dialysis nurses who are training new PD patients and their families. Adding medications A. Sterile procedure B. Heparin C. Antibiotics Daily Routine A. Recording pre and post BP (blood pressure) B. Recording pre and post weights Miscellaneous B. Bringing pro card and records... PD Training Manual Lesson 1-Starting PD Lesson 2-Hand hygiene Lesson 3-Caring for the Catheter Lesson 4-Steps for a Safe Treatment Lesson 5-Making Decisions About Your Child's Care Lesson 6-Balancing Your Fluids Lesson 7-Nutrition for Chronic Kidney Disease on PD Lesson 8-Dialysis Medications Lesson 9-Caregivers (cg) Subject: Medication Reconciliation Nursing Policy & Procedure No. Last revised/reviewed: 10/12 IV. Procedure Patient/care provider will be asked to complete the provided medication reconciliation form... ...The medications/list will be compared to the actual prescribed medications by the RN (Registered Nurse) or pharmacist... 1. PI # 4 was admitted for PD Home Therapy services on 1/18/2020 and dialyzed with an AMIA, a continuous PD cyclor. MR review revealed PD training documentation for the AMIA Automated PD System Training was completed (no date). There were PD training tests for sections 1,2 and 3 completed on 2/5/2020 and PD training tests for sections 4 and 5 were completed on 2/7/2020. There was no documentation PD training for lessons /sections 6-9, Fluids, Nutrition, Medications, and Caregivers were completed. Review of the record revealed Clinician nurse notes dated 8/10/2020 and 8/12/2020 which reported a future foster parent came to clinic for PD training. There was no documentation training/education was provided for lessons 6-9, Fluids, Nutrition, Medications and Caregivers. In an interview on 6/24/21 at 8:40 AM, EI (Employee Identifier) # 9, Registered Nurse, Home Therapy Training Nurse confirmed the training/education record documentation was not complete. 2. PI # 5 was admitted for PD Home Therapy services on 8/10/2020 and dialyzed with an APD (ambulatory) PD cyclor. Review of physician orders dated 2/3/21 revealed "restart" Epogen 1000 units sq (subcutaneous) every Monday and Friday. Review of the PD Training Checklist for Patient and /or Caregiver, Teach Back Moment and Scope Competency Review revealed no documentation the cg received training on Lesson 8, Dialysis Medications which included Anemia and the sq administration of Epogen. There was no successful return demonstration for the Epogen administration documented. In an interview on 6 /24/21 at 8:30 AM, EI # 9 confirmed there was no Epogen training and no return demonstration of Epogen administration documented in PI # 5's MR.

V0637

QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT
CFR(s): 494.110(a)(2)(ix)

The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must- (A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize

infection transmission, promote immunization; and (C) Take actions to reduce future incidents.

This STANDARD is not met as evidenced by:

Based on review of the Dialysis Facility Report for Fiscal Year (FY) 2021, facility hospitalization logs, February 2021 Exit Site/Peritonitis Apparent Cause Analysis Tools documentation, facility QAPI (quality improvement performance improvement) Meeting minutes and staff interviews, it was determined the IDT (interdisciplinary team) failed to ensure: 1) all exit site/peritonitis infection analysis included the potential contributing factors, lessons learned, and the action plan. 2) performance improvement actions were implemented and monitored when PD (peritoneal dialysis) infection rates trended upward. This affected PI (Patient Identifier) # 5 and had the potential to negatively affect all PD patients admitted to the facility. Findings include: Review of the Dialysis Facility Report for FY 2021 for Children's Hospital of Alabama ESRD (End Stage Renal Disease) 2019 rate of PD catheter-related infection was 4.2 per 100 PD patient-months, compared to 2.1 in Alabama, 2.7 in Network 8, and 2.1 nationally. Review of the facility January 2021 QAPI Meeting minutes for December 2020 Peritonitis and Tunnel Infections January 2020-December 2020 revealed the following: Total Patient month: January-218; February-228; March-236; April-247, May-260; June-274; July-290; August-304; September-319; October-335; November-348; December-363. Total Infection Episodes: January-15; February-16; March-18; April-19, May-19; June-21; July-23; August-23; September-23; October-23; November-23; December-24. Peritonitis Rate Total-January-14; February-14; March-13; April-13, May-13; June-13; July-13; August-13; September-14; October-14; November-15; December-15. In addition, the facility documented "PD Outcomes are Declining; Improvement Area, Yes; Action Plan Needed, Yes. If Yes, New Plan. The PD Infection Problems Statement was" Trend of increase tunnel infections. The Goal -Standardizing treatment of peritonitis, tunnel, and exit site infections. The Root Cause-Barriers documented were "Inconsistency of treatment for exit site infections." Review of the facility 2021 Hospitalization logs revealed in January 1 peritonitis hospitalization and 3 patients hospitalized for peritonitis in February 2021. Review of the facility QAPI Meeting Minutes documentation revealed in January 2021 there were 2 new Peritonitis infections and in February 2021 there were 3 new Peritonitis infections. There were no problem statements, goal, baseline data, root cause -Barriers documented. There was no action, start date, check point, end point documented and no responsible IDT members were identified. Review of facility documentation titled, Exit site/Peritonitis Apparent Cause Analysis Tool, included PI # 5 with the infection date 2/5/21, and an unsampled record with an infection date 2/11/21. There was no documentation the IDT identified potential contributing factors, lessons learned, and there was no action plan documented for 2 of 3 patients hospitalized February 2021 with exit site/peritonitis infections. Review of the QAPI Meeting Minutes documentation revealed 2 new Peritonitis infections in March 2021, in April 2021 2 new Peritonitis infections and in May 2021 there were 2 new Peritonitis infections and 1 tunnel infection reported. There were no problem statements, goals, baseline data root cause -barriers documented. There was no action, start date, check point, or end point documented, and no responsible IDT members were identified. In an interview on 6/24/21 at 1:55 PM, Employee Identifier # 1, Dialysis Coordinator the surveyor requested the facility action plan for improvement of PD infections. EI # 1 reported we review the numbers, discuss the cases each month and re-train the patient /caregiver. EI # 1 confirmed there was no documentation the facility implemented performance improvement actions and monitored the actions for effectiveness as identified during the January 2021 QAPI meeting.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

This STANDARD is not met as evidenced by:

Based on review of facility PD (peritoneal dialysis) medical records (MR), policy and procedure (p/p), and staff interviews it was determined the staff failed to ensure PD treatment record pre and post monitoring and medication delivery documentation was complete. This affected PI (Patient Identifier) # 5, 1 of 2 PD records reviewed and had the potential to negatively affect all PD patients treated at the facility. Findings include: Peritoneal Dialysis Home Self-Monitoring Departmental Policy No.18359 (No date documented) I. Purpose: The purpose is to provide guidelines for routine PD home self monitoring III. Policy The patient and/or caregiver (cg)...on how PD will complete training and agree to daily monitoring, recording, and reporting of health status information. VI. Equipment A. Blood pressure (BP) monitor B. Scale C. Home flowsheet VII. Procedure A. Family must complete the training plan for PD which includes parameter...set between the cg and...nephrologist....notify the PD nurse or physician if...values outside of these parameters... B. Each night before starting treatment the cg should take a pre blood pressure, weight, and heart rate. This should be written down on the home flowsheet. E. Once treatment is complete, the cg should record the post BP, weight and heart rate (HR)... PD Training Manual ...Lesson 8; Dialysis Medications In This Lesson You Will Learn... Anemia Treatment for Anemia If your child's hemoglobin level (a protein in the blood that contains iron and transports oxygen through the body) is less than 11, you will be trained on how and when to give this medication...Epogen... 1. PI # 5 was admitted for PD Home Therapy services on 8/10/2020 and dialyzed with an APD (ambulatory) PD cyclor. Review of physician orders dated 2/3/21 revealed "restart" Epogen 1000 units sq (subcutaneous) every Monday and Friday. MR review revealed March 1, 2021 to April 6, 2021 PD Self-Care Record documentation, the Daily Routine recording pre and post BP (blood pressure) and recording pre and post weights were not documented on the following dates: 3/3/21-no post BP 3/7/21- no post weight 3/8/21-no pre BP, pre HR (heart rate) 3/10/21-no pre BP, pre HR 3/11/21-no pre BP, no pre HR 3/13/21-no pre BP, pre HR 3/16/21-no pre BP, pre HR, post weight 3/18/21-no pre weight, pre BP, pre HR 3/19/21-no pre BP, pre HR 3/21/21-no pre HR 3/22/21-no pre BP, pre HR 3/24/21-no pre BP, pre HR, post BP, post HR 3/25/21-no pre BP, pre HR 3/26/21-no pre BP, pre HR, post BP, post HR 3/28/21-no pre BP, pre HR 3/29/21-no pre BP, pre HR 3/30/21-no pre BP, pre HR 3/31/21-no pre BP, pre HR 4/2/21-no post weight 4/4/21-no pre BP, pre HR, post weight 4/6/21-no pre BP, pre HR Further review of the PD Self-Care Record revealed the home therapy RN (Registered Nurse) initials on the Daily Routine document. There was no reason why the pre-post daily routine recording documentation was not completed and no documentation the home therapy RN counseled the cg on daily routine recording. There was no documentation Epogen sq twice weekly was administered during March. In an interview on 6/24/21 at 8:30 AM, Employee Identifier # 9, RN, Home Therapy Training Nurse confirmed there was no reason the pre-post treatment monitoring was not documented as required. EI # 9 reported BP and HR monitoring can be difficult with infants using an electronic

monitoring device and manual BP and HR monitoring was not taught to the cg. EI # 9 confirmed there was no documentation Epogen was administered in March and reported the facility has no policy for home Epogen administration documentation.