

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  012509	<b>(X3) Date Survey Completed</b>  03/30/2023
<b>Name of Provider or Supplier</b>  North Alabama Nephrology Center	<b>Street Address, City, State</b>  1311 North Memorial Parkway #200, Huntsville, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>  (Each deficiency should be preceded by full regulatory or LSC identifying information)
<b>V0634</b>	<p><b>QAPI-INDICATOR-MEDICAL INJURIES/ERRORS</b> CFR(s): 494.110(a)(2)(vi)</p> <p>The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.</p> <p>This STANDARD is not met as evidenced by: Based on observation, facility policy and procedure, facility Adverse Event (AE) Report dated 3/28/22 to 3/28/23, and staff interviews, it was determined the facility failed to ensure staff reported, documented, and investigated all AE's including a Near Miss per facility policy. This affected Patient Identifier (PI) # 11, one of three observations of access of AVF/AVG (arteriovenous fistula/graft) for initiation of dialysis and had the potential to negatively affect all patients who dialyzed at the facility. Findings include: Facility Policy: Patient Safety Event Reporting and Documentation Published: 02/06/2023 Reference Number: 61085 Version: 2 Purpose: The purpose of this policy is to provide guidelines for all clinical staff on identifying, reporting and documentation of patient related Near Misses, Safety Events (SE) and Serious Safety Events (SSE) in the In-Center...setting to: - Provide a standardized process for the identification and management of all patient related safety events - Promote a culture of safety ...Policy: When a Near Miss, SE or SSE occurs, staff are required to report, document, and review the event as noted in this policy. Staff are responsible for timely completion of these policy requirements. Procedure Reporting of any patient event...should occur in person or verbally and not be communicated via email or text message. Clinical Staff are required to report all SEs and SSEs to the patient's physician. State or local agencies should be notified in accordance with applicable state regulations... Near Miss...does not result in patient clinical harm, either through early detection or sheer luck. It is an unsafe situation that is indistinguishable from a safety event except for the outcome. Step 1. Clinical Staff to notify...Clinical Manager...Technical Services if applicable... Clinical Staff will</p>

perform documentation in the...medical record if appropriate, Patient Safety Data Entry Site Clinical Manager or facility designee will review during Quality Assessment and Performance Improvement. Documentation of all patient events shall be factual, complete, timely and concise...include patient assessment and represent an accurate recording of the events, times, interventions, and result of interventions... Careful consideration should occur when a late entry is necessary... 1. Review of the facility Adverse Events (AE) Report dated 3/28/22 to 3/28/23 revealed a total of seven SE's were documented, that included one fall, one clotted dialyzer, two needle dislodgements, one cardiac arrest, one blood loss and one access infiltration. 2. An observation of care was conducted on 3/29/23 at 10:10 AM at station 6 with EI (Employee Identifier) # 3, Registered Nurse, to initiate dialysis treatment for PI # 11, who had both a CVC (central venous catheter) and a new AVG. EI # 3 cleaned the AVG site with alcohol prep pads, picked up the Nipro Safety Needles from the chairside table, exited the station, then placed the Nipro Safety Needles into the trash can. In an interview on 3/29/23 at 10:12 AM, the surveyor asked EI # 3 what was wrong with the needles and why he/she discarded the unused needles? EI # 3 responded the needles were the wrong size. An interview was conducted on 3/30/23 at 7:30 AM with EI # 1, Facility Administrator. The surveyor requested facility SE/AE documentation for 3/29/23. EI # 1 provided SE/AE documentation dated 3/29/23 for one blood loss event. There was no documentation staff completed an AE/SE for the Near Miss observed on 3/29/23 at 10:15 AM. EI # 1 confirmed staff failed to complete required documentation for an AE/SE for the Near Miss.