

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 852584	(X3) Date Survey Completed 12/18/2020
Name of Provider or Supplier Mountainside Dialysis	Street Address, City, State 700 N Main Street, Jasper, GA	
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	An initial certification survey in conjunction with Covid 19 Focused Infection Control survey were conducted at Mountainside Dialysis on December 18, 2020. The surveys revealed that the facility was in compliance with 42 CFR Part 494.62 Conditions for Coverage for Emergency Preparedness Plan for End Stage Renal Disease Facilities. No deficiencies were cited.
V0000	An initial certification survey in conjunction with COVID-19 Focused Infection Control Survey were conducted at Mountainside Dialysis on December 18, 2020. The surveys revealed that the facility was not in compliance with 42 CFR Part 494.40 - Water and Dialysate Quality and 42 CFR 494.180 - Governance for End Stage Renal Dialysis Facilities. On December 18, 2020, a determination was made that a situation in which the facility's noncompliance with 494.40 - Water and Dialysate Quality, resulted in an Immediate Jeopardy (IJ) with potential harm to the health and safety of three of three patients who were undergoing hemodialysis treatment at the time of this observation. The facility in-center hemodialysis census was 4. The Facility Administrator and the Manager of Clinical Services were notified of the IJ finding on 12/18/20 at 10:30 a.m. The noncompliance related to the IJ was identified to have existed on 12/18/20 at 10:30 a.m. The IJ was abated during the survey on 12/18/20 at 1:30 p.m. when the facility implemented a Credible Allegation of Compliance related to the IJ. However, the Condition remained out of compliance. Also, the following standard level deficiency was cited:
V0175	CFC-WATER & DIALYSATE QUALITY CFR(s): 494.40 This CONDITION is not met as evidenced by: Based on observations, staff interviews, a review of the manufacturer's directions for use (DFU), and a review of the facility's Policy and Procedures (P&P), it was

determined that the facility failed to ensure that the water used for dialysis was accurately monitored, to provide safe treatments for all patients. On 12/18/20 at 10:30 a.m., a determination was made that a situation in which the facility's noncompliance with 42 CFR 494.40, Water and Dialysate Quality, resulted in an Immediate Jeopardy (IJ) with potential harm to the health and safety of three of three patients who were undergoing hemodialysis at the time of this observation. The facility in-center census was four. The Facility Administrator and the Manager of Clinical Services were informed of the IJ finding on 12/18/20 at 10:30 a.m. The noncompliance related to the IJ was identified to have existed on 12/18/20 at 10:20 a.m. The IJ situation was abated during the survey on 12/18/20 at 1:30 p.m., when the facility implemented a Credible Allegation of Compliance related to the IJ. Findings include: Cross Reference: V - 196 - Failure of the facility to ensure that staff accurately performed the Total Chlorine Test of water used for dialysis to ensure the water was safe for dialysis.

V0196

CARBON ADSORP-MONITOR, TEST FREQUENCY
CFR(s): 494.40(a)

6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet. Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.

This STANDARD is not met as evidenced by:
Based on observations, a review of the manufacturer's directions for use (DFU) for testing Total Chlorine (test for presence of Chlorine in the water used for dialysis) using the RPC (K100-0118 (/F) Ultra-Low Total Chlorine Test Strips, a review of the facility's Policy and Procedures (P&P), a review of the Total Chlorine logs, and staff interviews, it was determined that the facility failed to ensure that two of two Direct Patient Care staff (DPC AA and DPC BB, both licensed nurses) observed, who were assigned the task of testing and validation of the water quality, properly performed the Total Chlorine Test according to the manufacturer's DFU. Residual levels of Total Chlorine in the water used for dialysis may result in the destruction of patient's red blood cells (hemolysis) and could potentially cause serious physical harm to the patients. An immediate jeopardy (IJ) situation was identified on 12/18/20 at 10:20 a. m., with a potential for harm to the health and safety of three of three patients who were receiving hemodialysis treatment at the time of this observation, when both DPC AA and DPC BB, revealed a lack of knowledge of performing the Total Chlorine test procedure in compliance with the manufacturer's DFU. The Facility Administrator and the Manager of Clinical Services were informed of the IJ finding on 12/18/20 at 10:30 a.m. The IJ situation was abated on 12/18/20 at 1:30 p.m., when the facility implemented a Credible Allegation of Compliance related to the IJ that included DPC staff review and training, return demonstration, and successful completion of skills

competency checklists. Findings include: During observation of DPC AA's performance of the Total Chlorine test on 12/18/20 at 10:00 a.m., the following was observed: - DPC AA stated that the water temperature was 62 degrees Fahrenheit (F) and proceeded to obtain the water sample. Using a RPC Ultra-low Total Chlorine Test strip K100-0118, he dipped the test strip into the water sample and moved it back and forth for 20 seconds, then took it out and immediately compared it to the color chart. DPC AA stated he wanted to re-test again because he thought he should have dipped and moved the test strip for 30 seconds. During the second testing, DPC AA dipped and moved the RPC test strip back and forth for 32 seconds then immediately compared the test strip to the color chart. When asked if it was the manufacturer's DFU to compare the test strip to the color chart immediately after removing it from the sampled water, DPC AA stated on 12/18/20 at 10:10 a.m., "Yes, immediately". - During observation of DPC BB's performance of the Total Chlorine test on 12/18/20 at 10:45 a.m., the following was observed - DPC BB did not look at the water temperature gauge before performing the Total Chlorine test. Then DPC BB performed the Total Chlorine test without using a timer, clock, or watch. There was a clock in the Dialysate Preparation room next to the CM 130. DPC BB stated on 12/8/20 at 10:47 a.m., that she just counted 60 seconds in her head. - A review of the facility's Procedure: 2-05-02H, titled, "Total Chlorine Test Using RPC Ultra Low Total Chlorine Test Strip", with the latest revision date of April 2017, stated: Materials required: ... Stop watch, watch or clock with "second hand" Procedure: 2. Remove one strip from the foil package and dip it in the water sample for 60 seconds. While dipping the strip, move it back and forth at a constant gentle rate of approximately two, 1-2 inch wide strokes per second. Rationale: ... The water sample to be tested must be between 42 - 93 degrees F and utilize a 60 second dip time. NOTE: Refer to Manufacturer's Directions for Use for dip times based on water temperature ranges. 3. Remove the strip and shake once, briskly, to remove excess water. 4. Wait 20 seconds for the test strip color to develop... 5. After the 20 second wait period, immediately compare the strip color to the K100-0118 color chart... - A review of the Manufacturer's Directions for Use of RPC Ultra Low Total Chlorine Test Strip K100-0118 and K100-0118F, US Patent #6541269 (no date), stated: Temperature 62 degrees F - swish time 32 seconds... NOTE: As an alternative to measuring the water temperature and using the water temperature ranges to determine swish time for the test strip, it is acceptable to use a 60 second swish time to cover a 42 degrees F to 93 degrees F range of water temperature. - During a review of the Total Chlorine logs on 12/18/20 at approximately 12:18 p.m., it was revealed that there was a record of the Total Chlorine Test prior to the start of patient treatments on the first shift (patients were only dialyzing on first shift), on 12/18/20, performed by DPC AA. The IJ situation was abated when the Biomed and the Manager of Clinical Services conducted an in-service to both staff present, on the importance of following the manufacturer's DFU of Total Chlorine testing of water using RPC test strips, and completed skills competency with successful return demonstration using the clock, on each staff present. The water was retested in accordance to the manufacturer's DFU on 12/18/20 at 11:00 a.m. and was found to be safe to use for dialysis.

V0750

CFC-GOVERNANCE
CFR(s): 494.180

This CONDITION is not met as evidenced by:
Based on observations, staff interviews, a review of the manufacturer's directions for use (DFU), and a review of the facility's Policy and Procedures (P&P), it was

determined that the facility failed to ensure that the water used for dialysis was accurately monitored, to provide safe treatments for all patients. On 12/18/20 at 10:30 a.m., a determination was made that a situation in which the facility's noncompliance with 42 CFR 494.40, Water and Dialysate Quality, resulted in an Immediate Jeopardy (IJ) with potential harm to the health and safety of three of three patients who were undergoing hemodialysis at the time of this observation. The facility in-center census was four. The Facility Administrator and the Manager of Clinical Services were informed of the IJ finding on 12/18/20 at 10:30 a.m. The noncompliance related to the IJ was identified to have existed on 12/18/20 at 10:20 a.m. The IJ situation was abated during the survey on 12/18/20 at 1:30 p.m., when the facility implemented a Credible Allegation of Compliance related to the IJ. Findings include: Cross Reference: V - 196 - Failure of the facility to ensure that staff accurately performed the Total Chlorine Test of water used for dialysis to ensure the water was safe for dialysis.