STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152520	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 04/28/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA	710 PARK PL MISHAWAKA, IN 46545

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V000000		V000000		
	This was a federal ESRD recertification survey. Survey Dates: April 23, 24, 25, and 28, 2014. Facility #: 005883 Medicaid Vendor #: 200032320A Surveyors: Miriam Bennett, RN, BSN, PHNS Tonya Tucker, RN, BSN, PHNS Quality Review: Joyce Elder, MSN, BSN, RN April 30, 2014			
V000245	494.40(a) ACID CONC DIST-CONC LABELED & COLOR-CODED RED 5.5.3 Acid concentrate distribution systems: labeled & color-coded red Acid concentrate delivery piping should be labeled and color-coded red at the point of use (at the jug filling station or the dialysis machine connection). All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no rinsing or disinfection is necessary. More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains. Based on observation, interview, and policy review, the facility failed to ensure each treatment room station wall outlets for	V000245	The Area Manager and Clinical Manager met with the Medical Director on April 28, 2014 to review the survey statement of deficiencies and plan of	05/26/2014

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	dialysate were labeled to differentiate 2K and 3K outlets for 5 of 26 dialysis stations with the potential to affect all the facility's 133 patients. (stations # 1, 4, 5, 18, and 24) Findings include 1. During observation on 4/23/14 at 12:30 PM, dialysis station #1 wall outlets failed to contain labeling for the 2K and 3 K dialysate solution. a. Dialysis station #4 wall outlets failed to contain labeling for the 2K dialysate solution. b. Dialysis station #5 wall outlets failed to contain labeling for the 3K dialysate solution. c. Dialysis station #18 wall outlets failed to contain labeling for the 3K dialysate solution. d. Dialysis station #24 wall outlets failed to contain labeling for the 2K and 3K dialysate solution. 2. During interview on 4/23/14 at 12:45 PM, employee X indicated they check the orders tab, the wall outlet, and the machine when verifying the correct dialysate as ordered, but the 2K is always the outlet on the left second from right side and 3 K is on the right, and they think it is the same at other units. Employee X indicated the unit recently had the plumbing re-done on this end of the unit. 3. During interview on 4/23/14 at 12:50 PM, employee X indicated the dialysate outlets at the wall are supposed to be marked 3K at the very right, and 2 K to the left of that, and they know some are not marked. 4. The facility's policy titled "Concentrate		correction. **V245** The Director of Operations and the Clinical Manager met with Technical Department on April 23, 2014 regarding the proper labeling of the wall outlets for the dialysate. The Governing Body for the facility met on April 28, 2014 to review the Statement of Deficiencies regarding the acid concentrate delivery piping. The Director of Operations reviewed the following; FMS-CS-IC-II-140-310A "Concentrate Labeling Requirements Policy" with the Governing Body. After review of the policy, the Governing Body directed that the policy be reviewed and implemented with all staff. Staff members were educated by the Clinical Manager at the staff meeting on April 30, 2014 on the policy listed above, specifically focusing on the labeling of valve panels – valve panels or wall boxes must be labeled and color coded to identify the fluid that is delivered. These include the following: Water, Bicarbonate, and Acid/Granuflo. The Technical Department completed and verified the labeling of all wall boxes in the facility in accordance to the policy on April 24, 2014. The Clinical Manager also reviewed with all staff on April 30, 2014, his/her responsibility to notify the Clinical Manager or Charge Nurse immediately of any missing or unclear labeling. The	

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	Labeling Requirements," #FMS-CS-IC-II-140-310-A, revised 20-MAR-2013 states "Note: *If more than one product number or formula is in use at the facility, each acid concentrate dispensing outlet must use a differing color. ... Hemodialysis Concentrate Dissolution Units must use appropriate HMIS labeling. ... *If more than one acid is delivered, each must be identified by acid type. For example, 2K, 3K, or by catalog number; e.g., 3231, 2201 etc."		Technical Supervisor or designee will audit the labeling of the wall boxes in conjunction with the physical environment audits. Any issues of non-compliance will be corrected immediately and reported to the Clinical Manager. On a semi-annual basis, The Clinical Manager will be responsible for reporting on concentrate labeling per the QAI calendar. Ongoing compliance will be monitored by the QAI committee.	
V000543	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on clinical record review, policy review, and interview, the facility failed to ensure the Registered Nurse (RN) completed an assessment within 1 hour of starting dialysis for 8 of 10 records reviewed (#1, 3, 4, 6, 7, 8, 9, and 10), patients' blood pressures were monitored every 30 minutes for 1 of 10 records reviewed (#1), and changes in mental status and hypotension were reported to the RN for 1 of 10 records reviewed (#10) creating the potential to affect all 133 of the facility's current patients. Findings include: 1. Clinical record #1 included treatment sheets that evidenced the RN failed to round within 1 hour of the initiation of dialysis	V000543	**V543** The Clinical Manager provided an in-service to the patient care staff on April 30, 2014 to review the requirements of the following policies: FMS-CS-IC-I-110-149A “Nursing Supervision and Delegation Policy” and FMS-CS-IC-I-110-133A “Monitoring During Patient Treatment Policy”, emphasizing that patient evaluation by a nurse must be completed during the patient’s treatment, preferably within the first hour, and that vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed. The staff members acknowledged understanding of	05/26/2014

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	treatment and failed to evidence the patient's blood pressure had been checked at least every 30 minutes. A. The treatment sheet dated 4/11/14 evidenced the dialysis treatment started at 5:05 PM but the RN failed to assess the patient until 10:04 PM. B. The treatment sheet dated 4/16/14 evidenced the blood pressure had been checked at 6:32 PM and not again until 7:33 PM. C. The treatment sheet dated 4/18/14 evidenced the blood pressure had been checked at 6:07 PM and not again until 6:53 PM, then at 7:02 PM and not again until 8:02 PM. D. The treatment sheet dated 4/18/14 evidenced the dialysis treatment started at 4:59 PM and the RN evaluated the patient at 4:58 PM, prior to the initiation of dialysis. E. The treatment sheet dated 4/21/14 evidenced the dialysis treatment started at 5:09 PM and the RN evaluated the patient at 4:53 PM, prior to the initiation of dialysis. 2. Clinical record #6 contained a treatment sheet dated 3/28/14 that evidenced treatment was started at 1:24 PM and the RN did not assess the patient until 3:28 PM. A. The record contained a treatment sheet dated 3/31/14 that evidenced the treatment was started at 12:54 PM and the RN did not assess the patient until 3:21 PM. B. The record contained a treatment sheet dated 4/2/14 that evidenced the treatment		the policies. The Clinical Manager or designee will review treatment sheets daily x 2 weeks, then weekly x 4 weeks to ensure compliance with the policies. Any evidence of non-compliance will be addressed immediately including corrective action as appropriate. On-going monthly audits will also follow as part of the QAI program. The Clinical Manager is responsible for reviewing and analyzing all data prior to the QAI meeting and presenting it monthly to the QAI team; compliance will be monitored by the Governing Body. The Director of Operations is responsible to ensure the Clinical Manager presents all data as defined within the plan of correction to the QAI committee. The QAI committee is responsible to provide oversight and ensure resolution is occurring.	

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	was started at 12:57 PM and the RN did not assess the patient until 4:09 PM. C. The record contained a treatment sheet dated 4/18/14 that evidenced the treatment was started at 1:13 PM and the RN did not assess the patient until 3:02 PM. 3. Clinical record #7 contained a treatment sheet dated 3/29/14 that evidenced treatment was started at 11:25 AM and the RN did not assess the patient until 1:29 PM. 4. Clinical record #8 contained a treatment sheet dated 12/19/13 that evidenced treatment was started at 6:20 AM and the RN did not assess the patient until 10:04 AM. The record contained a treatment sheet dated 12/26/13 that evidenced the treatment was started at 6:24 AM and the RN did not assess the patient until 9:45 AM. 6. Clinical record #3 included treatment sheets that evidenced the RN failed to round within 1 hour of the initiation of dialysis treatment. A. The treatment sheet dated 4/4/14 evidenced the dialysis treatment started at 3:38 PM but failed to evidence the RN evaluated the patient until 7:32 PM. B. The treatment sheet dated 4/11/14 evidenced the dialysis treatment started at 11:44 AM but failed to evidence the RN evaluated the patient until 1:52 PM. C. The treatment sheet dated 4/21/14 evidenced the dialysis treatment started at			

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	3:13 PM, and the RN evaluated the patient at 2:58 PM, but failed to evidence the RN evaluated within 1 hour after the initiation of treatment. 7. Clinical record #4 included treatment sheets that evidenced the RN failed to round within 1 hour of the initiation of dialysis treatment. A. The treatment sheet dated 4/1/14 evidenced the dialysis treatment started at 5:52 PM but failed to evidence the RN evaluated the patient until 7:25 PM. B. The treatment sheet dated 4/5/14 evidenced the dialysis treatment started at 5:20 PM but failed to evidence the RN evaluated the patient until 6:44 PM. C. The treatment sheet dated 4/10/14 evidenced the dialysis treatment started at 5:37 PM but failed to evidence the RN evaluated the patient until 8:50 PM. 8. Clinical record #9 included treatment sheets that evidenced the RN failed to round within 1 hour of the initiation of dialysis treatment. A. The treatment sheet dated 1/20/14 evidenced the dialysis treatment started at 3:06 PM but failed to evidence the RN evaluated the patient until 9:47 PM. B. The treatment sheet dated 1/22/14 evidenced the dialysis treatment started at 3:41 PM but failed to evidence the RN evaluated the patient until 5:11 PM. C. The treatment sheet dated 1/27/14 evidenced the dialysis treatment started at			

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	3:36 PM but failed to evidence the RN evaluated the patient until 6:44 PM. D. The treatment sheet dated 1/29/14 evidenced the dialysis treatment started at 5:38 PM but failed to evidence the RN evaluated the patient until 6:30 PM. 9. Clinical record #10 included treatment sheets that evidenced the RN failed to round within 1 hour of the initiation of dialysis treatment. A. The treatment sheet dated 3/28/14 evidenced the dialysis treatment started at 3:57 PM but failed to evidence the RN evaluated the patient until 6:30 PM. The treatment sheet evidenced the patient's blood pressure ranged from 78-96/39-52 between 4:32-7:03 PM but failed to evidence the technician notified the RN, any further documentation of the findings, and that the RN discovered the low blood pressures upon review of the treatment records prior to patient leaving facility after dialysis. B. The treatment sheet dated 4/4/14 evidenced the dialysis treatment started at 4:00 PM but failed to evidence the RN evaluated the patient until 5:55 PM. C. The treatment sheet dated 3/31/14 evidenced at 8:03 PM, the patient was not responding to staff and blood pressure was in the 80's. The technician gave 200 milliliters Normal Saline and the patient responded then saying they were okay. The treatment sheet failed to evidence notification of the blood pressure and mental status to the RN, any further documentation of the findings, and that the RN discovered the low blood			

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	pressures upon review of the treatment records prior to patient leaving facility after dialysis. 10. During interview on 4/24/14 at 1:50 PM, employee A indicated the RN assessment should be done within the first hour of treatment. 11. During interview on 4/28/14 at 12:40 PM, employee A indicated normally if a patient can tolerate running with a lower blood pressure there would be a physician order saying this was okay. In regards to patient #10 there is not any further notes that the technician notified the RN, and there should also be a note that the blood pressure came up and the patient was stable. The RN should be looking for unusual findings in the treatment sheet before the patients leave. Employee A also indicated in regards to patient #10 not responding and having a low blood pressure, there was not documentation the RN was notified, and all those findings should have been reported and documented. 12. The facility's policy titled "Nursing Supervision and Delegation," #FMS-CS-IC-I-110-149A, revised 9/25/13 states, "Patient evaluation by the nurse must be completed during the patient's treatment, preferably within the first hour or as specified by stricter state regulations. ... Prior to discharge, the RN [registered nurse] must review the treatment record to: Confirm patient is stable for discharge, Identify facility processes or supervision that could result in adverse events. The record must be reviewed for: ... Low of high blood pressures [BP] ... Blood pressures <100 systolic or greater than 200 ... addressed by the registered nurse with or documentation			

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	present. ... Guidelines for PCT [patient care technician] / LPN [licensed practical nurse] / LVN [licensed vocational nurse] / RN: When to Refer a Patient to the Team Leader/Charge Nurse for Further Assessment ... Blood Pressure ... If B/P less than or equal to 100 mm/hg [millimeters of mercury] systolic during treatment. ... Mental Status Change in level of consciousness, confusion, lethargy, seizure, gait pattern, speech pattern, weakness or numbness at any time." 13. The facility's policy titled "Patient Monitoring During Patient Treatment," #FMS-CS-IC-I-110-133A, revised 7/4/12 states, "Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary. ... Vital Signs/Mental Status. ... Observe for changes in the patient's respirations, heart rate and blood pressure. Verify and react to unusual findings such as atypical blood pressure readings. Monitor for trends such as hypotension and bradycardia. Respond to changes in vital signs as indicated by patient's symptoms, nursing judgment or as ordered by the physician. Check for any changes in mental status, level of consciousness. ... Notifications. Unusual observations, findings and the inability to reach prescribed orders must be promptly reported to the charge nurse/team leader. Notify the physician as determined by the clinical judgment of the charge nurse/team leader. Documentation. Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record."			

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V000544	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE 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. Based on clinical record review, policy review, and interview, the facility failed to ensure blood flow rates had been maintained as ordered for 2 (# 1 and 4) of 10 records reviewed with the potential to affect all of the facility's 133 current patients. Findings include 1. Clinical record #1 included physician orders dated 2/14/14 that identified the blood flow rate (BFR) was to be 500 milliliters per minute. A. The treatment sheet dated 4/16/14 evidenced the BFR ran between 350 and 380 during the treatment with no reason documented for running it lower than ordered. B. The treatment sheet dated 4/18/14 evidenced the BFR ran between 380 and 390 during the treatment with no reason documented for running it lower than ordered. C. The treatment sheet dated 4/21/14 evidenced the BFR ran between 320 and 400 during the treatment with no reason documented for running it lower than ordered.	V000544	**V544** On April 30, 2014, the Clinic Manager and the Charge Nurse in-serviced the staff on the FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment Policy", with the emphasis on ensuring that the patient's treatment is delivered according to the physician's prescription. If staff is unable to achieve the prescribed Blood Flow Rate, the Patient Care Technician will document the reason and the interventions taken on the patient's flow sheet. The Patient Care Technician will also notify the RN of the inability to achieve the Prescribed Blood Flow Rate and document the notification on the flow sheet. The RN will assess the patient's access and notify the physician. Specific assessment, observations, interventions and follow-up, including outcomes, will be documented by the staff on the patient's flow sheet. The Clinical Manager or designee will review treatment sheets daily x 2 weeks, then weekly x 4 weeks to ensure that the patient's blood flow rate is delivered as prescribed; or if unable to achieve the prescribed blood flow rate, the	05/26/2014

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	2. Clinical record #4 included physician orders dated 3/22/14 that identified the blood flow rate (BFR) was to be 500 milliliters per minute. A. The treatment sheet dated 4/1/14 evidenced the BFR ran between 250 and 350 during the treatment with no reason documented for running it lower than ordered. B. The treatment sheet dated 4/5/14 evidenced the BFR ran at 350 during the treatment with no reason documented for running it lower than ordered. C. The treatment sheet dated 4/10/14 evidenced the BFR ran between 300 and 375 during the treatment with no reason documented for running it lower than ordered. D. The treatment sheet dated 4/12/14 evidenced the BFR ran between 300 and 350 during the treatment with no reason documented for running it lower than ordered. E. The treatment sheet dated 4/15/14 evidenced the BFR ran between 280 and 385 during the treatment with no reason documented for running it lower than ordered. F. The treatment sheet dated 4/17/14 evidenced the BFR ran between 300 and 365 during the treatment with no reason documented for running it lower than ordered. G. The treatment sheet dated 4/22/14 evidenced the BFR ran between 200 and 390		appropriate action taken is documented. On-going monthly audits will follow as part of the QAI program. The Clinic Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis and then develop a new Plan of Action if resolution is not occurring.	

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	during the treatment with no reason documented for running it lower than ordered. 3. During interview on 4/24/14 at 1:50 PM, employee A indicated the lower BFR runs should have documentation as to a reason for the reduction. 4. The facility's policy titled "Patient Monitoring During Patient Treatment," #FMS-CS-IC-I-110-133A, revised 7/4/12 states "Blood flow rate: Check prescribed blood flow is being achieved. Make adjustments as needed. ... Unusual observations, findings and the inability to reach prescribed orders must be promptly reported to the charge nurse/team leader. Notify the physician as determined by the clinical judgment of the charge nurse/team leader. Documentation. Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record."			