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<th>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</th>
<th>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER</th>
<th>MULTIPLE CONSTRUCTION</th>
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NAME OF PROVIDER OR SUPPLIER: FRESENIUS MEDICAL CARE TREE CITY
STREET ADDRESS, CITY, STATE, ZIP CODE: 999 N MICHIGAN AVE, GREENSBURG, IN 47240

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An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 484.22 for an ESRD Agency (Core) Federal Survey

Survey Date: 2-21-18, 2-23-18 and 2-26-18

Facility Number: 011758
Provider Number: 152624

Dialysis Agency Census:
In-Patient: 20
Home Peritoneal Dialysis: 2

At this Emergency Preparedness survey, Fresenius Medical Care Tree City Agency was found in compliance with Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers.

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This survey visit was for a federal ESRD (CORE) recertification and to review the agency's addition of a home peritoneal dialysis program.

Survey Dates: 2-21-18, 2-23-18 and 2-26-18

Facility ID # 011758
Provider ID # 152624

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STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

IDENTIFICATION NUMBER
152624

A. BUILDING
B. WING

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02/21/2018

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STREET ADDRESS, CITY, STATE, ZIP COD
999 N MICHIGAN AVE
GREENSBURG, IN 47240

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(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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PROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCES TO THE APPROPRIATE DEFICIENCY)

CROSS-REFERENCED TO THE APPROPRIATE

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Census: 20 In-Center hemodialysis patients
2 Home Peritoneal Dialysis patients

494.80(a)(3)
PA-IMMUNIZATION/MEDICATION HISTORY
The patient's comprehensive assessment must include, but is not limited to, the following:

Immunization history, and medication history.

Based on patient/family interview, clinical record review and facility record review the home peritoneal nurse failed to obtain an accurate medication history for 1 of 2 home peritoneal dialysis patients.

Findings Include:

1. An undated agency policy titled, "Review and Reconciliation of Medications Taken by Patients at Home Using MedReview-eRX" was reviewed and stated: "...Purpose: The purpose of this policy is to establish a process for identifying and documenting the most accurate list of medications the patient is taking at home (non-facility provided medications). This policy applies to both in-center and home patients ... Responsibility: Medication review: Registered Nurse (RN) ... Dialysis patients may have multiple medications, prescribed by multiple prescribers, with frequent changes to their regimen. Review and reconciliation are done to confirm health care providers have current medication information... The assessment should demonstrate that all current medications were reviewed for possible adverse effects/interactions and continued needs ...."

2. The clinical record of Patient # 1, a home
peritoneal dialysis patient with an admission date of 2-10-17 and first dialysis of 10-1-17, was reviewed with the following findings:

A. An agency document titled, "MedReview-eRx Mini Medication Report" was reviewed. The document failed to evidenced eye drops, hemorrhoid ointment, Melatonin (natural sleep aide) or Tylenol (mild pain/fever medication). The record indicated the patient took Furosemide (a water pill) 40 mg [milligrams] as follows: 1 1/2 tablet by mouth once a day (to equal 60 mg).

B. A medication list provided by the patient indicated he/she was to take the Furosemide 40 mg tablet as follows: 1 tablet once a day.

3. An interview with the patient was conducted 2-23-18 at 8:59 AM. The patient was asked to review the medications listed on the agency Mini Medication Report. He/she reported this list was accurate, except he/she was taking Furosemide 40 mg 1 tablet daily. The patient was asked if there were any other medications he/she used at home and the patient reported taking Melatonin at night for sleep, Tylenol as needed for pain, eye drops for dry eyes after cataract surgery, and hemorrhoid ointment. During this time, the home peritoneal nurse, employee H, reported he/she had not been aware of the change for the Furosemide dosage or that the patient was using eye drops, Melatonin, Tylenol or hemorrhoid medications at home.

Record Review
Emphasis was placed on:
Medication Reconciliation performed on a monthly basis per policy.
Effective 2.28.18 Program Manager or designee will conduct monthly audits utilizing PD Medical Chart Audits for 3 months. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done per QAI calendar.
The Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate.
The in-service sheets are available in the clinic for review.
The deficiency was corrected on 3.20.18506

494.90(a)(5)
POC-VASCULAR ACCESS-MONITOR/REFERRALS
The interdisciplinary team must provide vascular access monitoring and appropriate,
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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| V 0550 | V550 | POC-VASCULAR ACCESS-MONITOR/REFERRALS | On 2.22.18, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:
- FMSCSICI105001A: Initiation of Treatment Using an Arteriovenous Graft or Fistula and Optiflux Single Use Ebeam Dialyzer Policy
- FMSCSICI105001C: Initiation of Treatment Using an Arteriovenous Graft or Fistula and Optiflux Single Use Ebeam Dialyzer Procedure
- FMSCSICI115006A: Assessment and Preparation of Internal Access for Needle Placement Policy
- FMSCSICI115006C: Assessment and Preparation of Internal Access for Needle Placement Procedure

Emphasis was placed on:
- Dialysis Access cleansing for 30 seconds prior to initiation of treatment per policy.
Effective 3.15.18, Clinical Manager or designee will conduct monthly

Findings Include:

1. An agency policy titled, "Assessment and Preparation of Internal Access for Needle Placement" was reviewed and stated: "... preparation of sites for needle placement ... perform hand hygiene and don gloves ... use an approved antiseptic to clean the insertion site ... using gentle friction, clean the access sites beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry before cannulating ...."

2. During a chair side observation on 2-21-18 at 7:30 AM, Employee I was preparing the access site for Patient # 5. During the procedure Employee I cleansed one access site for 15 seconds and the other site for 5 seconds. During the procedure, the employee touched the computer and then the patient during the initiation of treatment without glove change or hand hygiene.

3. An interview with Employee I was conducted on 2-21-18 at 11:30 AM. Employee I reported the timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.
policy for the scrub was 15 seconds to each site. Employee I indicated he / she did not realize he / she had scrubbed 15 seconds on one site and 5 seconds of the other. The employee failed to follow agency policy to scrub each site 30 seconds.

4. An interview with the Clinical Manager was conducted on 2-21-18 at 8:34 AM. The clinical manager reported the employee should have changed gloves and performed hand hygiene after touching the computer and before touching the patient.

494.100(a)(3)

H-TRAIN CONTENT INCLUDES ER PREP
HOME PTS

The training must-
(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:
(i) The nature and management of ESRD.
(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in audits utilizing Treatment Initiation Audit Form for 3 months. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Treatment Initiation Audit Form per QAI calendar. The Clinical Manger is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The in-service sheets are available in the clinic for review. The deficiency was corrected on 3.20.18.
Based on record review and interview, the home peritoneal nurse failed to assure home dialysis patients (Patient #1 and 2) understood they must complete the peritoneal dialysis flow sheets to include the type of Dialysate used each treatment and bring in this documentation to each clinic visit to be placed in the patient's clinical record for 2 of 2 peritoneal dialysis patient.

Findings Include:

1. An agency policy titled, "Patient Home Record Keeping" was reviewed and stated: "The purpose of this procedure is to provide direction for documentation of dialysis treatments for home dialysis patients... Procedure for Maintaining Home Patient Records... 1. Train patients and/or patient caregivers to complete assessments and to fill out home treatment log sheets as part of initial home dialysis training. 2. Provide patients with blank copies of home treatment log sheets and a binder for keeping records at home. 3. Teach patients to bring binder and completed home training log sheets to the Home Dialysis unit for monthly clinic visits to be reviewed by Home Program nursing staff and/or physicians. 4.
Patients using cyclers equipped with data cards will also be taught to enter data properly into cycler software and to bring he data cards with them to clinic visits each month. 5. Place copies of home treatment logs in patient medical record. Patients will document treatments on paper treatment logs or on data cards. Document review of log in progress note as part of monthly clinic visit."

2. An agency policy titled, "Documentation of Health Data for Home Therapies" was reviewed and stated: "... The home therapies team must ensure that the patient creates a treatment record for every dialysis treatment. Data will be reviewed by the home therapies nurse and all concerns addressed and documented in the medical record. All pertinent patient communication must be entered into the patient’s medical record. Transmitted data from the Patient Portal will be reviewed by the home therapies nurse...to verify data transmission and review for actionable data...If actionable data is identified and additional actions are required, the home therapies nurse...will contact the patient and or care partner, and document any interventions, including patient instructions and or physician notifications."

3. On 2-23-18 a clinical record review and interview was conducted with home (PD) peritoneal dialysis Patient # 1, with an admission date of 10-2-17 and first dialysis on 10-1-17 with the following findings:

A. On 2-21-18 the home PD cycler data recorded by the patient, from 11-15-17 to 1-22-18, failed to evidence the type of Dialysate solution (Dextrose 1.5%, 2.5% or 4.25%) used during the treatment. The clinical record failed to evidence documentation by the patient indicating the
solution he/she had used during his/her daily PD exchanges.

B. An interview was conducted with Patient #1 on 2-23-18 at 8:59 AM. The patient reported he/she would put all information in the computer and had a flash drive he/she would bring to the clinic twice monthly.

4. On 2-26-18 a clinical record review for home PD Patient #2 and interview was conducted with the caregiver of Patient #2, with an admission date of 8-21-17 and first dialysis 8-17-17 with the following findings:

A. On 2-26-18 the home PD cycler data recorded by Patient #2's caregiver, from 9-27-17 to 1-22-18, failed to evidence the type of Dialysate solution (Dextrose 1.5%, 2.5% or 4.25%) used during the treatment. The clinical record failed to evidence documentation by the patient/caregiver indicating the solution he/she had used during his/her daily PD exchanges.

B. An interview with the Patient #2's caregiver was conducted on 2-26-18. The caregiver reported he/she would set up the cycler daily for the patient and recorded all information. The caregiver was asked about recording the type of Dialysate used with each treatment and the education he/she had received. The caregiver reported he/she the solution was not recorded at times and "they told me to write it down last week."

5. An interview was conducted on 2-23-18 at 1:30 PM with the home PD coordinator, administrator, clinical supervisor and home PD nurse regarding the absence of home PD flow sheets for the Dialysate solution used during treatments for
Patient #1 and Patient #2. The home PD coordinator, administrator, clinical supervisor and home PD nurse reported they failed to get the patient's home documentation for the agency clinical record.

494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS The dialysis facility must -
(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and
(3) Maintain this information in the patient’s medical record.

Based on record review and interview, the dialysis facility failed to retrieve and review data as well as maintaining the information in the patient’s medical record in for 2 of 2 peritoneal dialysis patient. (#1 and 2)

Findings Include:

1. An agency policy titled, "Patient Home Record Keeping" was reviewed and stated: "The purpose of this procedure is to provide direction for documentation of dialysis treatments for home dialysis patients ... Procedure for Maintaining Home Patient Records ... 1. Train patients and/or patient caregivers to complete assessments and to fill out home treatment log sheets as part of initial home dialysis training. 2. Provide patients with blank copies of home treatment log sheets and a binder for keeping records at home. 3. Teach patients to bring binder and completed home training log sheets to the Home Dialysis unit for monthly clinic visits to be reviewed by Home Program nursing staff and/or physicians. 4.
### Statement of Deficiencies and Plan of Correction

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#### Summary Statement of Deficiency

Patients using cyclers equipped with data cards will also be taught to enter data properly into cycler software and to bring the data cards with them to clinic visits each month. Patients will document treatments on paper treatment logs or on data cards. Document review of log in progress note as part of monthly clinic visit.

2. An agency policy titled, "Documentation of Health Data for Home Therapies" was reviewed and stated: "... The home therapies team must ensure that the patient creates a treatment record for every dialysis treatment. Data will be reviewed by the home therapies nurse and all concerns addressed and documented in the medical record. All pertinent patient communications must be entered into the patient’s medical record. Transmitted data from the Patient Portal will be reviewed by the home therapies nurse...to verify data transmission and review for actionable data...If actionable data is identified and additional actions are required, the home therapies nurse will contact the patient and /or care partner, and document any interventions, including patient instructions and /or physician notifications...."

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   A. On 2-21-18 the home PD cycler data recorded by the patient, from 11-15-17 to 1-22-18, failed to evidence the type of Dialysate solution (Dextrose 1.5 %, 2.5% or 4.25 %) used during the treatment. The clinical record failed to evidence documentation by the patient indicating the compliance. Within compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Clinical Manger is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The in-service sheets are available in the clinic for review. The deficiency was corrected on 3.20.18
solution he/she had used during his/her daily PD exchanges.

B. An interview was conducted with Patient #1 on 2-23-18 at 8:59 AM. The patient reported he/she would put all information in the computer and had a flash drive he/she would bring to the clinic twice monthly.

4. On 2-26-18 a clinical record review for home PD Patient # 2 and interview was conducted with the caregiver of Patient # 2, with an admission date of 8-21-17 and first dialysis 8-17-17 with the following findings:

A. On 2-26-18 the home PD cycler data recorded by Patient #2's caregiver, from 9-27-17 to 1-22-18, failed to evidence the type of Dialysate solution (Dextrose 1.5%, 2.5 % or 4.25%) used during the treatment. The clinical record failed to evidence documentation by the patient/caregiver indicating the solution he/she had used during his/her daily PD exchanges.

B. An interview with the Patient #2's caregiver was conducted on 2-26-18. The caregiver reported he/she would set up the cycler daily for the patient and recorded all information. The caregiver was asked about recording the type of Dialysate used with each treatment and the education he/she had received. The caregiver reported he/she the solution was not recorded at times and "they told me to write it down last week."

5. An interview was conducted on 2-23-18 at 1:30 PM with the home PD coordinator, administrator, clinical supervisor and home PD nurse regarding the absence of home PD flow sheets for the Dialysate solution used during treatments for
Patient #1 and Patient #2. The home PD coordinator, administrator, clinical supervisor and home PD nurse reported they failed to get the patient's home documentation for the agency clinical record.

494.150(c)(1) MD RESP-DEVELOP, REVIEW & APPROVE P&P
The medical director must-
(1) Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility;
Based on observation, record review, and interview, the dialysis facility medical director failed to ensure infection control policies were clear, did not conflict with each other and were consistent to direct staff in the performance of procedures in 1 of 1 agency.

Findings include:

1. An agency document regarding the Governing body Guidelines was reviewed and stated, "The Governing Body is directly responsible for the ongoing governance and day to day operations of the dialysis facility. The purpose of these Guidelines are to direct each facility's Governing Body members on the Governing Body's federally mandated responsibilities as well as those actions required by [Agency Corporation name]... Specific Roles and Responsibilities : Medical Director ... is responsible for direct management and oversight of the following facility programs and processes ... initial and ongoing review and adoption of policies and procedures ...."

2. An agency policy issued 3-20-13 and titled "Hand Hygiene" was reviewed and stated, " ...The purpose of this policy is to prevent transmission
### Summary Statement of Deficiency

3. An agency procedure dated 1-6-14 and titled "Initiation of Treatment Using a (CVC) Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" was reviewed and stated: "...Prior to Initiation: Assessment and Machine Parameters: 1. Perform hand hygiene and put on gloves and protective gown... 7. Enter the total fluid goal and prescribed time in the dialysis machine... 8. Enter other prescribed treatment parameters... in the dialysis machine... Before proceeding to change the catheter dressing, put on full face shield with mask... Put mask on patient... At anytime during the initiation process, if gloves are visibly contaminated, remove gloves, perform hand hygiene and don new gloves..."

4. An agency policy dated 1-6-14 and titled "Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" was reviewed and stated: "...Infection Control... Employees must follow hand hygiene practices to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination... Hands will be decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water: Before and after direct patient contact with patients, Entering and leaving the treatment area, before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications, immediately after removing gloves, after contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hand are not visibly soiled, after contact with inanimate objects near the patient, and when moving from a contaminated body site to a clean body site of the same patient..."
5. On 2-23-18 at 7:44 AM, during an observation of an initiation of a central venous catheter at station #4, by Employee E, to in-center hemodialysis patient #10, the following was observed:

   A. Employee L, performed hand hygiene and applied gloves, removed old dressing from catheter site and discarded dressing, removed gloves and performed hand hygiene, touched the computer (an inanimate object) and resumed procedure without removing gloves or performing hand hygiene before touching the patient again.

   B. An interview with Employee L, after the procedure on 2-23-18 at 8:15 AM, was conducted. Employee L was queried on why he/she did not change gloves and perform hand hygiene after touching the computer and before touching the patient's central line tubing or site. Employee L stated, "this is per policy, hand hygiene is not necessary after touching computer."

6. An interview was conducted with Employee N, the education coordinator. The educator reported the hemodialysis machine being used at the agency are "T" machines and considered a closed system. Disinfection with bleach was performed prior to patient use. Employee N reported glove change and hand hygiene was necessary only if hands were viably soiled. When queried Employee N on the different policies and their meaning (CVC initiation procedure refered to the hand hygiene policy and the hand hygiene policy required hand hygiene and a glove change if an inanimate object (ie: a computer) was touched), Employee L indicated the policies could be cross contamination according to Hand Hygiene Policy".
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**MULTIPLE CONSTRUCTION**

**DATE SURVEY COMPLETED**: 02/21/2018

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**EVENT ID**: L22M11  **FACILITY ID**: 011758