STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152515	A. BUILDING _____ B. WING _____	C 09/09/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE FORT WAYNE JEFFERSON	**7836 W JEFFERSON BLVD STE LL10 FORT WAYNE, IN 46804**

(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
E 000	Initial Comments An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 494.62. Dates: September 7, 8, 9; 2021 Facility #: 005160 Provider #: 152515 Census: 49 At this Emergency Preparedness survey, Fresenius Medical Care Fort Wayne Jefferson was found not in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.	E 000		
E 022	Policies/Procedures for Sheltering in Place CFR(s): 494.62(b)(3) §403.748(b)(4), §416.54(b)(3), §418.113(b)(6)(i), §441.184(b)(4), §460.84(b)(5), §482.15(b)(4), §483.73(b)(4), §483.475(b)(4), §485.68(b)(2), §485.625(b)(4), §485.727(b)(2), §485.920(b)(3), §491.12(b)(2), §494.62(b)(3). (b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC facilities]. At a minimum, the policies and procedures must address the	E 022		

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

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E 022	Continued From page 1 following:] [(4) or (2),(3),(5),(6)] A means to shelter in place for patients, staff, and volunteers who remain in the [facility]. *[For Inpatient Hospices at §418.113(b):] Policies and procedures. (6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following: (i) A means to shelter in place for patients, hospice employees who remain in the hospice. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure its emergency preparedness plan contained a means to directly provide food and water to patients, staff, and volunteers, in the event they would have to shelter in place, which had the potential to affect all patients, staff, and volunteers. Findings include: 1. An agency policy, titled "Guidelines for Shelter-in-Place During Emergencies" and dated 1/16/18, indicated but was not limited to " ... Policy: When it becomes apparent that an external danger may result in injury, possible exposure, or loss of life to patients, visitors, and staff, the Clinical Manager (CM) or designee ... is responsible for directing facility occupants to shelter-in-place ... Actions for Shelter-in-Place ... 6. Notify local authorities (police or fire) of shelter-in-place and: ... Explain no food supplies ... is available, expected capability to maintain shelter-in-place is not more than 12 hours ...."	E 022		

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E 022	Continued From page 2 2. An agency document, titled "Annual Notification Requirement - Local Emergency Operations Center" and dated 9/25/2020, was reviewed on 9/9/21. The Administrator confirmed the document was a "notification letter" sent annually to the county's Emergency Operations Director which requested "assistance with resources if the need arises." The document indicated but was not limited to " ... [Fresenius Medical Care Fort Wayne Jefferson has] contracts or supply arrangements with local water supply companies to provide tanker water if needed ... Clearly our interest is to be able to continue to provide life sustaining dialysis and support services to our patients ... in the event our resources are exhausted, we ask to be given priority for assistance with ... supplies, obtaining water ... and in severe situations with arranging transportation for staff and patients ...." 3. An interview was conducted on 9/9/21 at 1:11 PM with the Nurse Director. During the interview, the Nurse Director confirmed the facility did not have any emergency water or food supplies on site. 4. An interview was conducted on 9/9/21 at 3:31 PM with the Administrator. During the interview, the Administrator confirmed if the facility was to shelter-in-place, the Emergency Preparedness Plan directed staff to "notify the appropriate individuals that we do not have any food supplies on hand and would need immediate assistance."	E 022		
V 000	INITIAL COMMENTS This was a Federal ESRD CORE recertification and complaint survey completed on September 9, 2021.	V 000		

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V 000	Continued From page 3 Dates: September 7, 8, 9; 2021 Facility #: 005160 Provider #: 152515 Complaint #: IN00270419 - Substantiated In-Center Census: 49 Home Therapy Census: 35 Total Patients all Modalities: 84	V 000		
V 113	IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1) 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. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure staff followed hand hygiene infection control practices for 4 of 6 observations (RN #1, RN #2, PCT #1). Findings include: 1. An agency policy, titled "Hand Hygiene" and dated 11/4/19, indicated but was not limited to " ... Hands will be ... decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water ... when ... entering and leaving the treatment area ... immediately after removing gloves ...."	V 113		

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V 113	Continued From page 4	V 113		

2. Centers for Disease Control and Prevention (CDC, Revised 6/10/21). "When & How to Wash Your Hands." Retrieved 9/10/21 from www.cdc.gov. " ... Five Steps to Wash Your Hands ... 3. Scrub your hands for at least 20 seconds ...."

3. During an observation on 9/8/21 at 7:50 AM at dialysis station 8, Registered Nurse (RN) #1 was observed caring for Patient #6. The employee was observed entering the station and donned gloves. RN #1 failed to perform hand hygiene upon entering the station and prior to donning gloves.

4. During an observation on 9/8/21 at 8:13 AM at dialysis station 23, Patient Care Technician (PCT) #1 was observed caring for Patient #12. The employee was observed removing their gloves, obtained gauze from the station's supply drawer, placed the gauze on the patient's side table, performed hand hygiene with alcohol-based hand rub, and donned new gloves. PCT #1 failed to complete hand hygiene immediately after gloves were removed.

5. During an observation on 9/8/21 at 11:35 AM at dialysis station 6, RN #2 was observed caring for Patient #10. The nurse assessed the patient's access site with their stethoscope, removed their gloves, wiped the stethoscope with an alcohol pad, then donned new gloves. After RN #2 had completed their care with the patient, the nurse removed their gloves and washed their hands for 15 seconds.

6. During an observation on 9/8/21 at 11:45 AM at dialysis station 9, RN #1 was observed caring for Patient # 11. The nurse completed their care,

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V 113	Continued From page 5 removed their gloves, walked to dialysis station 8, donned gloves, and began to provide care to Patient #6. The staff member failed to perform hand hygiene when removing gloves, leaving a station, entering a station, and before donning gloves. After RN #1 had completed their care with the patient, the nurse removed their gloves and washed their hands for 15 seconds. 7. An interview was performed on 9/9/21 at 11:57 AM with the Nurse Director. During the interview, the Nurse Director confirmed staff should remove their gloves prior to leaving a station and staff should perform hand hygiene after removing gloves and in between glove changes. The Nurse Director also confirmed staff should wash their hands for "30 seconds."	V 113		
V 407	PE-HD PTS IN VIEW DURING TREATMENTS CFR(s): 494.60(c)(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure site access was visible for the duration of the treatment for 2 of 8 station observations (#7, 21). Findings include: 1. An agency policy, titled "Patient Assessment and Monitoring" and dated 9/29/18, indicated but was not limited to " ... Monitoring During Treatment ... Follow the steps below for monitoring patient and machine parameters	V 407		

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V 407	Continued From page 6 during treatment: ... Step 1 ... Access: Observe connections are secure and visible ... Ensure access remains uncovered throughout the treatment ...." 2. During an observation on 9/8/21 at 11:06 AM at dialysis station 7, Patient #13's access site was not visible. 3. During an observation on 9/8/21 at 11:08 AM at dialysis station 21, Patient #3's access site was not visible. 4. An interview was performed on 9/9/21 at 11:57 AM with the Nurse Director. During the interview, the Nurse Director confirmed site access should be visible at all times during a dialysis treatment.	V 407		
V 504	PA-ASSESS B/P, FLUID MANAGEMENT NEEDS CFR(s): 494.80(a)(2) The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to evidence the patient's blood pressure (BP) was obtained at the ordered frequency and failed to ensure the Registered Nurse (RN) was notified for blood pressure being out of parameters for 2 of 10 patient records reviewed (#3, 14). Findings include:	V 504		

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V 504	Continued From page 7 1. An agency policy, titled "Patient Assessment and Monitoring" and dated 9/29/18, indicated but was not limited to " ... Pre-Treatment Assessment and Data Collection: Pre-Treatment: Direct patient care staff may collect pre-treatment ... BP ... If the PCT [Patient Care Technician] ... notes any changes or abnormal findings in the patient's condition ... the patient care technician must report the changes in the patient condition to a registered nurse who will further assess the patient prior to initiation of the treatment ... During Treatment: The Registered Nurse will assess/re-assess any findings addressed pre or during treatment as needed .... Monitoring During Treatment: Obtain blood pressure ... every 30 minutes or more as needed but not to exceed 45 minutes ... Record blood pressure. Recheck blood pressures after a drop that requires interventions such as administering normal saline. Reposition electronic cuff or use a manual cuff for aberrant blood pressure readings. Report to the nurse: Systolic [first number on BP reading] blood pressures greater than 180 mm/Hg. Diastolic [second number on BP reading] blood pressure greater than 100 mm/Hg. Blood Pressure less than or equal to 100 mm/hg systolic ...." 2. An agency policy, titled "Determination of Blood Pressure" and dated 7/4/12, indicated but was not limited to " ... Policy: Obtain blood pressure reading pre-treatment, every 30 minutes or more during hemodialysis, post treatment, and as needed ... Verify by repositioning electronic cuff or use a manual cuff ... when a large drop or elevation in blood pressure is noted ... Background: ... The following conditions can lead to serious outcomes and even death ... Untreated/unattended severe hypertension [high	V 504		

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blood pressure] (>200 systolic) ... Untreated/unattended severe hypotension [low blood pressure] (<80 systolic) ...."

3. An undated, untitled agency document, confirmed by the Nurse Director on 9/9/21 at 12:58 PM as the facility's blood pressure parameters, indicated the "Lower" limit for blood pressure was "100"/"50" and the "Upper" limit for blood pressure was "180"/"100."

4. The clinical record of Patient #3 was reviewed on 7/9/21. The record included a "Treatment Sheet" for the patient's hemodialysis treatment completed on 8/27/21. The Treatment Sheet indicated Patient #3's treatment was started at 10:30 AM and their blood pressure was 71/47 at 11:13 AM. PCT #3 indicated the blood pressure recheck was 65/36 at 11:16 AM. At 12:07 PM, Patient #3's blood pressure was 63/42, and RN #3 indicated the patient's treatment goal was adjusted and 100 milliliters (ml) of Normal Saline was given in response to the patient's low blood pressure. The patient's blood pressure at 12:11 PM was 69/36, and RN #3 indicated "[Patient #3] denies complaints; resting comfortably ... bp improving ...." At 12:33 PM, PCT #3 indicated " ... pt [patient] stable, no complaints." Patient #3's next blood pressure reading was documented at 1:08 PM (61/42). PCT #3 indicated they repositioned the patient's blood pressure cuff to the patient's ankle and the blood pressure recheck was 77/45 at 1:11 PM. PCT #3 indicated the patient's remaining blood pressure readings during the dialysis treatment were 75/48 at 1:33 PM, 75/49 at 2:02 PM, 85/55 at 2:33 PM, and 88/47 at 2:36 PM. The documentation failed to evidence PCT #3 notified the RN of the patient's multiple low blood pressure readings, and staff

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failed to follow policy by obtaining the patient's blood pressure at minimum every 30 minutes.

The clinical record included a "Treatment Sheet" for Patient #3's hemodialysis treatment completed on 8/25/21. The Treatment Sheet indicated at the start of treatment (11:08 AM) Patient #3's blood pressure was 144/93. During the patient's first check at 11:40 AM, the blood pressure was indicated by PCT #4 to be 73/45. PCT #4 indicated " ... RN notified ... [Patient #3] denies complaints; Patient ... feels fine ... recheck in 5 minutes per RN." At 11:47 AM, PCT #4 indicated the patient's blood pressure was 72/45, the RN was notified, and the PCT was advised to obtain the patient's blood pressure "every 10 minutes per RN." Patient #3's blood pressure was obtained at 12:05 PM (66/45), 12:06 PM (76/49), 12:20 PM (68/38), 12:21 PM (87/40), 12:57 PM (88/58), 13:06 PM (80/50), 1:23 PM (84/51), 1:40 PM (71/50), 1:54 PM (87/58), 2:05 PM (92/50), 2:38 PM (89/59), 3:01 PM (80/53), and 3:09 PM (117/83). The documentation failed to evidence Patient #3's blood pressures were obtained at the increased frequency ordered by the RN.

5. The clinical record of Patient #14 was reviewed on 9/8/21 and included a "Treatment Sheet" for the hemodialysis treatment completed on 9/2/21. The Treatment Sheet indicated PCT #3 obtained Patient #14's pre-treatment assessment, and the patient's blood pressure while sitting was 190/125 and 206/127 while standing. PCT #3 started the patient's dialysis treatment at 11:58 AM. During treatment, PCT #3 indicated Patient #14's blood pressures were 190/115 (12:01 PM), 184/113 (1:30 PM), 209/113 (2:31 PM), 203/126 (3:00 PM), 185/136 (3:32

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V 504	Continued From page 10 PM), and 214/141 (3:45 PM). The documentation failed to evidence the PCT notified the RN of Patient #14's elevated blood pressure prior to the start of treatment and during treatment. 6. An interview was conducted on 9/9/21 at 11:57 with the Nurse Director. The Nurse Director confirmed the patient's blood pressure should be obtained every 30 minutes while on treatment and the RN should be notified by the PCT of a blood pressure outside of parameters (both high and low) "initially ... unless [the blood pressure reading was] typical for the patient." The Nurse Director confirmed patients should have their blood pressure obtained "every 15 minutes" if a blood pressure reading below parameters was obtained. The Nurse Director also confirmed patients should have their blood pressures obtained "every 15 minutes" when a blood pressure reading above parameters was obtained and the patient had symptoms of high blood pressure (headache, dizziness, etc).	V 504		
V 715	MD RESP-ENSURE ALL ADHERE TO P&P CFR(s): 494.150(c)(2)(i) The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by: Based on record review and interview, the medical director failed to ensure staff followed all facility policies to ensure patients were	V 715		

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discharged with blood pressure (BP) readings only within set parameters for 1 of 10 records reviewed (#14).

Findings include:

1. An agency policy, titled "Patient Assessment and Monitoring" and dated 9/29/18, indicated but was not limited to " ... Post- Treatment: ... the [Patient Care Technician] must report the changes in the patient condition to a registered nurse [RN] who will further assess the patient prior to discharge after treatment. An abnormal finding confirmed by the RN will be reported to the attending physician if necessary as determined by the clinical judgement of the registered nurse for assessment and intervention ... Post-Treatment: Assessment and Data Collection: ... Ensure vital signs and overall condition are stable for discharge ...."

2. An agency policy, titled "Determination of Blood Pressure" and dated 7/4/12, indicated but was not limited to " ... Policy: Obtain blood pressure reading ... post treatment, and as needed ... Verify by repositioning electronic cuff or use a manual cuff ... when a large drop or elevation in blood pressure is noted ... Background: ... The following conditions can lead to serious outcomes and even death ... Untreated/unattended severe hypertension (>200 systolic) ...."

3. An undated, untitled agency document, confirmed by the Nurse Director on 9/9/21 at 12:58 PM as the facility's blood pressure parameters, indicated the "Upper" limit for blood pressure was "180"/"100."

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V 715	Continued From page 12 4. The clinical record of Patient #14 was reviewed on 9/8/21 and included a "Treatment Sheet" for the hemodialysis treatment completed on 9/2/21. The Treatment Sheet indicated the Nurse Director obtained the patient's post-dialysis blood pressures at 3:48 PM. Patient #14's blood pressure while sitting was 214/141 and blood pressure while standing was 206/118. The Nurse Director indicated they had noted the patient's elevated blood pressure, the patient denied signs and symptoms of high blood pressure and reported "he would take BP meds when he gets home ... [Patient] left in stable [condition] ...." The document failed to evidence the patient's physician was notified of the elevated blood pressure prior to discharge. 5. An interview was conducted on 9/9/21 at 11:57 with the Nurse Director. The Nurse Director confirmed a physician order must be obtained if the patient's post-treatment blood pressure was higher than parameters.	V 715		