STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152538	A. BUILDING _____ B. WING _____	07/28/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE TRI COUNTIES	**817 S 13TH ST DECATUR, IN 46733**

(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 A Recertification (CORE) and COVID-19 Focused Infection Control Survey was conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare and Medicaid (CMS). An unannounced on-site Recertification and Focused Infection Control Survey (ASPEN #69ID11) conducted at the above-named End Stage Renal Disease (ESRD) facility from 07/26/21 to -07/28/21 resulted in a finding of substantial compliance respective to the Emergency Preparedness Program Condition for Coverage (CfC) under 42 CFR 494.62 with the following standard-level deficiencies listed below. Survey Dates: 07/26/21-07/28/21 Total Facility Census: 36 In-Center Hemodialysis: 36 Home Hemodialysis (HHD): 0 Peritoneal Dialysis (PD): 0 Nocturnal: 0 Pediatrics: 0 Sample Size: 4 Network 9 was contacted after entrance.	E 000		
E 039	EP Testing Requirements CFR(s): 494.62(d)(2) §416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.102(d)(2), §485.68(d)(2),	E 039		

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

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E 039	Continued From page 1 §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §491.12(d)(2), §494.62(d)(2). *[For ASCs at §416.54, CORFs at §485.68, OPO, "Organizations" under §485.727, CMHCs at §485.920, RHCs/FQHCs at §491.12, and ESRD Facilities at §494.62]: (2) Testing. The [facility] must conduct exercises to test the emergency plan annually. The [facility] must do all of the following: (i) Participate in a full-scale exercise that is community-based every 2 years; or (A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or (B) If the [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event. (ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or individual, facility-based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the [facility's] response to and	E 039		

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E 039	Continued From page 2 maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [facility's] emergency plan, as needed. *[For Hospices at 418.113(d):] (2) Testing for hospices that provide care in the patient's home. The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following: (i) Participate in a full-scale exercise that is community based every 2 years; or (A) When a community based exercise is not accessible, conduct an individual facility based functional exercise every 2 years; or (B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full scale community-based exercise or individual facility-based functional exercise following the onset of the emergency event. (ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or a facility based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (3) Testing for hospices that provide inpatient care directly. The hospice must conduct exercises to test the emergency plan twice per	E 039		

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E 039	Continued From page 3 year. The hospice must do the following: (i) Participate in an annual full-scale exercise that is community-based; or (A) When a community-based exercise is not accessible, conduct an annual individual facility-based functional exercise; or (B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in its next required full-scale community based or facility-based functional exercise following the onset of the emergency event. (ii) Conduct an additional annual exercise that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or a facility based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop led by a facilitator that includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the hospice's emergency plan, as needed. *[For PRFTs at §441.184(d), Hospitals at §482.15(d), CAHs at §485.625(d):] (2) Testing. The [PRTF, Hospital, CAH] must conduct exercises to test the emergency plan twice per year. The [PRTF, Hospital, CAH] must do the following: (i) Participate in an annual full-scale exercise that is community-based; or (A) When a community-based exercise is not accessible, conduct an annual individual,	E 039		

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E 039	Continued From page 4 facility-based functional exercise; or (B) If the [PRTF, Hospital, CAH] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in its next required full-scale community based or individual, facility-based functional exercise following the onset of the emergency event. (ii) Conduct an [additional] annual exercise or and that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or individual, a facility-based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the [facility's] response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the [facility's] emergency plan, as needed. *[For PACE at §460.84(d):] (2) Testing. The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following: (i) Participate in an annual full-scale exercise that is community-based; or (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or (B) If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from	E 039		

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E 039	Continued From page 5 engaging in its next required full-scale community based or individual, facility-based functional exercise following the onset of the emergency event. (ii) Conduct an additional exercise every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or individual, a facility based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed. *[For LTC Facilities at §483.73(d):] (2) The [LTC facility] must conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills using the emergency procedures. The [LTC facility, ICF/IID] must do the following: (i) Participate in an annual full-scale exercise that is community-based; or (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise. (B) If the [LTC facility] facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging its next required a full-scale community-based or	E 039		

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E 039	Continued From page 6 individual, facility-based functional exercise following the onset of the emergency event. (ii) Conduct an additional annual exercise that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or an individual, facility based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the [LTC facility] facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [LTC facility] facility's emergency plan, as needed. *[For ICF/IIDs at §483.475(d)]: (2) Testing. The ICF/IID must conduct exercises to test the emergency plan at least twice per year. The ICF/IID must do the following: (i) Participate in an annual full-scale exercise that is community-based; or (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or. (B) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event. (ii) Conduct an additional annual exercise that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or	E 039		

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E 039	Continued From page 7 (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed. *[For HHAs at §484.102] (d)(2) Testing. The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following: (i) Participate in a full-scale exercise that is community-based; or (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise every 2 years; or. (B) If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in its next required full-scale community-based or individual, facility based functional exercise following the onset of the emergency event. (ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group	E 039		

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E 039	Continued From page 8 discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed. *[For OPOs at §486.360] (d)(2) Testing. The OPO must conduct exercises to test the emergency plan. The OPO must do the following: (i) Conduct a paper-based, tabletop exercise or workshop at least annually. A tabletop exercise is led by a facilitator and includes a group discussion, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. If the OPO experiences an actual natural or man-made emergency that requires activation of the emergency plan, the OPO is exempt from engaging in its next required testing exercise following the onset of the emergency event. (ii) Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the [RNHCI's and OPO's] emergency plan, as needed. *[RNCHIs at §403.748]: (d)(2) Testing. The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following: (i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or	E 039		

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E 039	Continued From page 9 prepared questions designed to challenge an emergency plan. (ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed. This Standard is not met as evidenced by: Based on review of the facility's Emergency Preparedness (EP) Plan, staff interview, and review of the facility's policy, the facility failed to ensure participation in an annual exercise and analysis of that exercise to test the facility's Emergency Preparedness Plan. Failure to test the activation of the emergency plan could lead to a missed opportunity to discover the need for revision of the plan in order to improve its effectiveness. Findings include: Review of the facility's "Emergency Preparedness Plan," revealed the most recent documentation of the facility's emergency preparedness exercise was dated 06/02/20. During an interview and review of the EP Plan with the Clinical Manager (CM) on 07/26/21 at 2:35 PM, the CM stated that no documentation of an exercise, or attempt to complete one, of the Emergency Preparedness Plan since 06/02/20 could be located. The CM agreed no drill had been conducted during the most recent 12-month period and stated, "We should have had one by 06/02/21. I have one planned for August, but we are late." Review of the facility's EP Plan (approved by the Governing Body, 03/17/20), under the heading, "Staff Preparedness, To do's," revealed, "Conduct at least one Table Top Mock drill annually with the	E 039		

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E 039	Continued From page 10 entire IDT [Interdisciplinary Team] involvement; Participate in at least one community based emergency drill. . .If a community based drill is not completed each year, the DO [Director of Operations] must document who they contact, what was the reason given on why the drill could not be completed."	E 039		
V 000	INITIAL COMMENTS A Recertification (CORE) and COVID-19 Focused Infection Control survey was conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare & Medicaid Services (CMS). An unannounced on-site Recertification (CORE) and Focused Infection Control survey, (ASPEN #69ID11), conducted at the above-named End Stage Renal Disease (ESRD) facility from 07/26/21 to 07/28/21 resulted in a finding of substantial compliance respective to applicable Conditions for Coverage (CfC) under 42 CFR 494, Subpart A through D with the following standard-level deficiencies listed below. Total Facility Census: 36 In-Center Hemodialysis: 36 Home Hemodialysis (HHD): 0 Peritoneal Dialysis (PD): 0 Nocturnal: 0 Pediatrics: 0 Sample Size: 4 Network 9 was contacted after entrance.	V 000		

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V 122	IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL CFR(s): 494.30(a)(4)(ii) [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. This Standard is not met as evidenced by: Based on observation, staff interview, and review of the facility's policy and procedure, the facility failed to ensure the staff thoroughly disinfected all surfaces of the dialysis stations during four of four observations of the disinfection process. The failure to thoroughly disinfect dialysis stations has the potential to transmit blood borne pathogens and infections, and negatively impact all 36 patients receiving inpatient hemodialysis at the facility. Findings include: Observations of the Patient Treatment Area conducted on 07/26/21 revealed the following: At 9:10 AM at Station 1, Patient Care Technician (PCT) 8 cleaned the dialysis station (which includes the patient chair and dialysis machine) with bleach solution after it was vacated by an unsampled patient. PCT 8 failed to wipe the Hansen connectors (used to connect the tubing that allows the flow of the dialysis fluid into and out of the dialyzer) and failed to wipe the interior of the blood pump chamber (which holds blood tubing during treatment).	V 122		

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V 122	Continued From page 12 At 9:24 AM at Station 3, PCT 9 cleaned the dialysis station with bleach solution after it was vacated by an unsampled patient. PCT 9 failed to wipe the Hansen connectors and failed to wipe the interior of the blood pump chamber. At 10:12 AM at Station 2, PCT 8 cleaned the dialysis station with bleach solution after it was vacated by an unsampled patient. PCT 8 failed to wipe the Hansen connectors and failed to wipe the interior of the blood pump chamber. At 10:38 AM at Station 8, PCT 7 cleaned the dialysis station with bleach solution after it was vacated by an unsampled patient. PCT7 failed to wipe the Hansen connectors and attached tubing, failed to wipe the top of the intravenous (IV) pole, and failed to wipe the laminated information sheets hanging on the IV pole. During a joint interview with the Clinical Manager (CM) and Director of Operations (DOO) on 07/27/21 at 9:42 AM, the above observations were reviewed. The CM and DOO that facility expectation and policy are for all parts of the dialysis station to be disinfected between patient uses. Review of the facility's policy titled, "Cleaning and Disinfection of the Dialysis Station," revised date 11/02/20, revealed, "The dialysis station could become contaminated with blood and other body fluids during treatment. After use, all non-disposable equipment and supplies must be disinfected with 1:100 bleach or manufacturer's recommendations or discarded ...Externally disinfect the dialysis machine with 1:100 bleach solution after each dialysis treatment. Refer to Cleaning of the Dialysis Station Procedure."	V 122		

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FRESENIUS MEDICAL CARE TRI COUNTIES	817 S 13TH ST DECATUR, IN 46733

(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
V 122	Continued From page 13 Review of the facility's procedure titled, "Cleaning and Disinfection of the Dialysis Station," revised 11/04/19, revealed, "Use a cloth wetted with 1:100 bleach solution. . .to clean and disinfect the dialysis station (chair/bed, tables, machine, television, IV pole, B/P [blood pressure] cuff, hand sanitizer dispenser and holder, etc.)"	V 122		