STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152681	A. BUILDING _____ B. WING _____	C 09/01/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FORT WAYNE NORTH DIALYSIS	**415 E DUPOND RD FORT WAYNE, IN 46825**

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E 000	Initial Comments An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 494.62. Survey Date: 9/1/21 Facility #: 14068 Provider #: 152681 Census = 36 At this Emergency Preparedness survey, Fort Wayne North Dialysis was found not in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.	E 000		
E 030	Names and Contact Information CFR(s): 494.62(c)(1) §403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.102(c)(1), §485.68(c)(1), §485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1). [(c) The [facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least every 2 years [annually for LTC facilities]. The communication plan must include all of the following:] (1) Names and contact information for the following: (i) Staff.	E 030		

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

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E 030	Continued From page 1 (ii) Entities providing services under arrangement. (iii) Patients' physicians (iv) Other [facilities]. (v) Volunteers. *[For Hospitals at §482.15(c) and CAHs at §485.625(c)] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians (iv) Other [hospitals and CAHs]. (v) Volunteers. *[For RNHCIs at §403.748(c):] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Next of kin, guardian, or custodian. (iv) Other RNHCIs. (v) Volunteers. *[For ASCs at §416.45(c):] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians. (iv) Volunteers. *[For Hospices at §418.113(c):] The communication plan must include all of the following: (1) Names and contact information for the	E 030		

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E 030	Continued From page 2 following: (i) Hospice employees. (ii) Entities providing services under arrangement. (iii) Patients' physicians. (iv) Other hospices. *[For HHAs at §484.102(c):] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians. (iv) Volunteers. *[For OPOs at §486.360(c):] The communication plan must include all of the following: (2) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Volunteers. (iv) Other OPOs. (v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA). This Standard is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure the emergency evacuation kit contained current patient information per the agency's emergency preparation plan. Findings include: A policy titled "Facility Emergency Management Plan [Incenter Hemodialysis, Home]," indicated " ...Each evacuation kit[s] should contain ... Copy of each patient's treatment orders and medication list ... FA [Facility Administrator] or designee will verify patient information is updated and replace	E 030		

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E 030	Continued From page 3 at least monthly ...." During an observation on 9/1/21 at 11:05 AM, the emergency kit was observed to contain 36 [thirty-six] patient information sheets dated 7/2/21. During an interview on 9/1/21 at 4:30 PM, when asked how often the Kardex in the black emergency prep binder, in the emergency kit, on the floor needed to be updated, the Administrator indicated "monthly."	E 030		
V 000	INITIAL COMMENTS This visit was a Federal ESRD CORE Recertification and complaint survey. Survey dates: August 31, & September 1; 2021 Facility #: 14068 Provider #: 152681 Complaint #: IN00315086; Substantiated with findings Complaint #: IN00347154; Substantiated with findings In-Center Census: 36 Home Therapy Census: 0 Total Patients all Modalities: 36	V 000		
V 112	IC-CDC MMWR 2001 CFR(s): 494.30(a) The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in	V 112		

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V 112	Continued From page 4 "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009. This Standard is not met as evidenced by: Based on observation, record review, and interview, the agency failed to follow standard infection control precautions for 1 of 2 observed fistula cannulations (Registered Nurse D). Findings include: A policy titled "AV [Arteriovenous] or Graft Cannulation with JMS Sysloc® Mini Safety Fistula Needles [SFN] and Administration of Heparin	V 112		

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V 112	Continued From page 5 Loading Dose," indicated " ...Procedure ... While maintaining aseptic technique, prep planned needle sites by applying a 70% alcohol prep pad to each site using a circular rubbing motion, center out ... Do not palpate insertion site once area has been prepped ...." During an observation on 9/1/21 at 8:56 AM at dialysis station 7, Registered Nurse D, was observed caring for patient #7. Employee was observed touching fistula access site after cleaning it with a 70% alcohol prep pad, proceeded to cannulate without cleaning the site again. During an interview on 9/1/21 at 4:30 PM, when asked if staff should touch an access site after it's been cleaned, but before they cannulate it, the Administrator indicated "no."	V 112		
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 observations, record review, and interview, the agency failed to ensure staff followed hand hygiene infection control practices for 1 of 4 staff observations (Patient Care Technician C). Findings include: 1. A policy titled "Infection Control For Dialysis Facilities," indicated " ...Hand hygiene is to be	V 113		

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V 113	Continued From page 6 performed ... after removal of gloves ... and on exiting the patient treatment area ...." 2. During an observation on 9/1/21 at 9:45 AM at dialysis station 3, Patient Care Technician C, was observed caring for patient #6. Employee was observed not performing hand hygiene after removing gloves. 3. During an observation on 9/1/21 at 10:45 AM at dialysis station 4, Patient Care Technician C, was observed caring for patient #7. Employee was observed not performing hand hygiene after removing gloves. 4. During an observation on 9/1/21 at 11:00 AM at dialysis station 5, Patient Care Technician C, was observed caring for patient #5. Employee was observed not performing hand hygiene after removing gloves. 5. During an interview on 9/1/21 at 4:30 PM, when asked if staff should complete hand hygiene after taking off gloves, the Administrator indicated "yes."	V 113		
V 147	IC-STAFF EDUCATION-CATHETERS/CATHETER CARE CFR(s): 494.30(a)(2) Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.	V 147		

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V 147	Continued From page 7 II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. This Standard is not met as evidenced by: Based on observations, record review, and interview, and the agency failed to ensure that staff followed infection control policies for 2 of 2 observations of Central Venous Catheter (CVC) care. (Patient Care Tech C). Findings include: 1. A policy titled "Central Venous Catheter [CVC] with Clearguard HD Antimicrobial End Caps Procedure," indicated " ...Use dialysis precautions and aseptic technique throughout procedure ... Device Disinfectant and Skin Antiseptic: 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol ... Effective For: CVC access exit site ... Effective Volume: 1 prepackaged swab ... Effective Contact time: 30 seconds back and forth motion ... Air Drying Time: 60 seconds ... Procedure ...	V 147		

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V 147	Continued From page 8 Holding catheter with non-dominant hand and using aseptic technique, clean exit site with 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol swab for a minimum of 30 seconds, apply to the CVC site in a back and forth pattern, using gentle friction, progressing from insertion site to the periphery using both sides of the swab ... Then wait 60 seconds for air dry time ... Clean each CVC limb/cap with a new LARGE [sic] alcohol prep pad, starting close to the exit site and finishing with the cap ...apply label to the dressing indicating ... date dressing change was performed ...." 2. During an observation on 9/1/21 at 10:00 AM at dialysis station 3, Patient Care Technician C, was observed caring for patient #6. Employee was observed cleaning an insertion site for a central venous catheter and did not clean the site in a back-and-forth pattern using gentle friction, progressing from insertion site to the periphery, using both sides of the swab. 3. During an observation on 9/1/21 at 11:30 AM at dialysis station 6, Patient Care Technician C, was observed caring for patient #6. Employee was observed cleaning an insertion site for a central venous catheter and did not clean the site in a back and forth pattern. 4. During an interview on 9/1/21 at 4:30 PM, when asked what the proper CVC cleaning technique is, the Administrator indicated it was to take off dressing, assess site, use chloroprep to clean from inside out cleaning back and forth, then clean the ports from insertion site to end tubes with alcohol pad.	V 147		
V 240	BICARB DISTRIBUTION SYS-USE OF UV CFR(s): 494.40(a)	V 240		

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V 240	Continued From page 9 5.5.4 Bicarbonate concentrate distribution systems: use of UV UV irradiation devices that are used to control bacteria proliferation in the pipes of bicarbonate concentrate distribution systems should be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm2. The device should be sized for the maximum anticipated flow rate according to the manufacturer's instructions and be equipped with an on-line monitor of radiant energy output that activates a visual alarm indicating that the lamp should be replaced. Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output. Disinfection of the bicarbonate concentrate distribution system should continue to be performed routinely. This Standard is not met as evidenced by: Based on observation, record review, and interview, the agency failed to ensure that pH and conductivity was tested via the phoenix meter before initiation of dialysis for 4 of 4 staff observations (Patient Care Technician's B, C, E and, Registered Nurse D). Findings include: 1. A policy titled "Testing pH and Conductivity of Proportioned Dialysate and Verification of Temperature of Proportioned Dialysate," indicated " ...Manual pH testing must be performed prior to each patient treatment ...." 2. During an observation on 9/1/21 at 10:20 AM,	V 240		

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	152681	A. BUILDING _____ B. WING _____	C 09/01/2021

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V 240	Continued From page 10 Patient Care Technician B, was observed cleaning and disinfecting station 6. Employee was observed not performing manual pH testing prior to ensuring machine was ready for patient use. 3. During an observation on 9/1/21 at 9:45 AM at dialysis station 3, Patient Care Technician C, was observed caring for patient #6. Employee was observed not performing manual pH testing prior to patient treatment initiation. 4. During an observation on 9/1/21 at 8:56 AM at dialysis station 7, Registered Nurse D, was observed caring for patient #7. Employee was observed not performing manual pH testing prior to patient treatment initiation. 5. During an observation on 9/1/21 at 8:51 AM, Patient Care Technician E, was observed cleaning and disinfecting station 6. Employee was observed not performing manual pH testing prior to ensuring machine was ready for patient use. 6. During an interview on 9/1/21 at 4:30 PM, when asked if phoenix meters needed to be used before each patient treatment, the Administrator indicated "yes."	V 240		
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 agency failed to ensure site access	V 407		

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V 407	Continued From page 11 was always visible for 3 of 11 station observations (#6, 8, 9). Findings include: 1. A policy titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment," indicated " ...The vascular access site, blood line connections and the patient's face should always be visible throughout the dialysis treatment ...." 2. During an observation on 9/1/21 at 11:00 AM, patient #6's access site was not visible. 3. During an observation on 9/1/21 at 11:00 AM, patient #8's access site was not visible. 4. During an observation on 9/1/21 at 11:00 AM, patient #9's access site was not visible. 5. During an interview on 9/1/21 at 4:30 PM, when asked if access sites needed to be visible at all times, the Administrator indicated "yes."	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 agency failed to ensure the licensed nurse was notified for blood pressure being out of parameters for 1 of 5 patient records reviewed (#1). Findings include:	V 504		

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V 504	Continued From page 12 1. A policy titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment," indicated " ...Unless other abnormal parameters are established by the facility Governing Body and documented in the Governing Body minutes, the following are considered abnormal findings and should be reported to the licensed nurse and documented in the patient's medical record ... Blood Pressure Post Treatment ... If the patient can stand ... Standing systolic BP [blood pressure] greater than 140 mm/Hg ... Standing diastolic BP greater than 90 mm/Hg ... Sitting BP for patient's [sic] that cannot stand ... Sitting systolic BP greater then 140 mm/Hg ... Sitting diastolic BP greater than 90 mm/Hg...." 2. The record of patient #1 was reviewed on 9/1/21 at 11:45 AM. The treatment sheet indicated " ...Vitals ... Blood Pressure Sit ... Post-treatment ... 204/93 ... Blood Pressure Stand ... Post-treatment ... 202/87 ...." The record did not evidence nurse notification of a blood pressure out of policy appropriate parameters. 3. During an interview on 9/1/21 at 4:30 PM, when asked if a nurse should've been notified about a blood pressure of 223/95, the Administrator indicated "yes."	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;	V 715		

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V 715	Continued From page 13	V 715		

This Standard is not met as evidenced by:
Based on observation, record review, and interview, the agency medical director failed to ensure staff followed all facility policies to ensure all expired medication was discarded, all multiuse medications had an opened date on them, and needles were re-capped appropriately to avoid injury for 1 of 2 medication preparations observed (Patient Care Technician D).

Findings include:

1. A policy titled "Medication Policy," indicated " ...All medications are checked monthly for expiration dates ... Disposal of expired medications, including over the counter and nutritional product samples are removed from the treatment and inventory areas and disposed of per state/local regulations ...."

2. A policy titled "Preparation and Administration of Parenteral Medications With All Dialyzer Types," indicated " ...Recap the needle using a two-handed aseptic recapping technique ...."

3. During an observation on 9/1/21 at 8:50 AM, Patient Care Technician D was observed drawing up heparin into a syringe and while placing cap back on she held cap in one hand and needle in other hand to push the two together (incorrect technique).

4. During an observation on 9/1/21 at 10:45 AM, 14 [fourteen] influenza vaccines (expiration date 6/30/21), 2 (two) Nepro with Carb Steady Shakes (expiration date 4/1/21), and 1 (one) Nepro Shake Vanilla (expiration 8/1/21), were observed to be present in the facility floor medication refrigerator.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152681	A. BUILDING _____ B. WING _____	C 09/01/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FORT WAYNE NORTH DIALYSIS	415 E DUPOND RD FORT WAYNE, IN 46825

(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 715	Continued From page 14 5. Additionally, 2 (two) opened bottles of Cinacalcet and 1 (one) opened bottle of Loperamide 2 mg (milligram) were observed to have no opened date written on them. 6. During an interview on 9/1/21 at 4:30 PM, when asked if expired flu shots and nepro shakes needed to be discarded from the floor supply, the Administrator indicated "yes." When asked if any open medications needed to be marked with an open date, the Administrator indicated "yes." Additionally, the administrator stated when recapping needles staff should have the lid on the hard surface and use the needle to" scoop" the needle's cap on and then push to secure it on the needle.	V 715		