STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152673	A. BUILDING _____ B. WING _____	C 04/05/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
DUNELAND DIALYSIS MICHIGAN CITY	3727 N FRONTAGE ROAD MICHIGAN CITY, IN 46360

(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 000	INITIAL COMMENTS This visit was for a Federal Complaint survey of an ESRD supplier conducted by the Indiana Department of Health. Survey dates: 04-05-2023 Complaint # IN00396987; a deficiency was cited. ICHD 12 month unduplicated census: 49 Home Peritoneal Dialysis census: 6 Home Hemodialysis census: 0 Total census: 55 Duneland Dialysis Michigan City was found not to have been in compliance with the requirements of 42 CFR 494 et seq. in relation to the complaint survey.	V 000	*POC accepted 4-13-2023* *Deborah Franco, RN*	
V 800	QR by Area 3 on 04-10-2023 COVID-19 Vaccination of Facility Staff CFR(s): 494.30 (b)(1)-(3)(i)-(x) § 494.30 Condition: Infection control. (b) COVID-19 Vaccination of facility staff. The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of	V 800		5/5/23

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 04/12/2023

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V 800	Continued From page 1	V 800		

a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.
(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:
(i) Facility employees;
(ii) Licensed practitioners;
(iii) Students, trainees, and volunteers; and
(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.
(2) The policies and procedures of this section do not apply to the following facility staff:
(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section; and
(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section.
(3) The policies and procedures must include, at a minimum, the following components:
(i) A process for ensuring all staff specified in paragraph (b)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19

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V 800	Continued From page 2	V 800		

vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients;
(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;
(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (b)(1) of this section;
(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;
(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;
(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:
(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the

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V 800	Continued From page 3	V 800		

contraindications; and
(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

Effective 60 Days After Publication:
(ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;
This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the facility failed to ensure staff adhered to the facility's COVID-19 policy and contingency plan related to Personal Protective Equipment (PPE) use by employees exempt from Covid-19 vaccination, for 1 of 1 (Patient Care Technician #2) observed on the treatment floor.

Findings Include:

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V 800	Continued From page 4 1. A review of an agency policy dated 1-27-2022, titled, 'COVID-19 VACCINATION AND EXEMPTION POLICY,' stated, " ... (5) Reasonable Accommodations. All facilities must have a contingency plan and prioritize the plan for staff who have not been fully vaccinated but have an approved exemption. Actions or job modifications for these staff may include but are not limited to: ... c. Requirement to wear N 95 or KN 95 masks at all times while in a U.S. Renal Care facility." 2. A review of an agency document titled, 'ANNUAL EMPLOYEE FILE TRACKER,' indicated PCT #2 was exempt from COVID-19 vaccination. 3. On 4-05-2023 at 11:50 AM, during an interview, PCT #2 was noted to be wearing a blue surgical mask while on the treatment floor and providing patient care. 4. On 4-05-2023 at 4:10 PM, when queried as to what precautions an exempt employee should be expected to practice in the facility, the regional administrator indicated they were expected to be wearing masks, face shields, gowns, and gloves. When queried further as to what extra precautions exempted staff were expected to take according to the facility policy, the regional administrator was unaware that N 95 masks were required by facility policy to be worn by vaccine exempt employees.	V 800		