

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152518	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 06/03/2022
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE WARSAW		STREET ADDRESS, CITY, STATE, ZIP COD 3334 LAKE CITY HWY WARSAW, IN 46580		
(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 0000 Bldg. 00	<p>An Emergency Preparedness survey was conducted by the Indiana Department of Health, in accordance with 42 CFR 484.62 for End Stage Renal Disease providers.</p> <p>Survey Dates: 5/31/22, 6/1/22, 6/2/22, and 6/3/22</p> <p>Facility: 005163</p> <p>CCN: 152518</p> <p>Census by Service Type: In Center Hemodialysis: 49 Home Hemodialysis: 3 Home Peritoneal dialysis: 12 Total Patients all Modalities: 64 Stations: 12</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Warsaw was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 484.62.</p> <p>QA: Area 2 June 14, 2022</p>	E 0000		
V 0000 Bldg. 00	<p>This visit was for a CORE Federal recertification survey of an ESRD provider.</p> <p>Survey Dates: May 31, June 1, 2, 3, 2022</p> <p>Facility: 005163</p>	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosed days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 0113 Bldg. 00	<p>CCN: 152518</p> <p>Census by Service Type: In Center Hemodialysis: 49 Home Hemodialysis: 3 Home Peritoneal Dialysis: 12 Total Patients all Modalities: 64</p> <p>QA: Area 2 June 14, 2022</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE 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.</p> <p>Based on observation, interview, and record review the facility failed to ensure staff provided care in accordance with the facility's infection control and hand hygiene policies and procedures, in 4 of 4 observation days [5/31/22, 6/1/22, 6/2/22, and 6/3/22], creating the potential to affect all the facility's 49 current incenter patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. During observation day #1 on 5/31/22, observed PCT #4 at 10:55 AM in Station #5, where a patient had finished a hemodialysis treatment. PCT #4 was observed with gloved hands to remove the bloodlines from the dialysis machine and disposal, then PCT #4 removed their gloves and donned clean gloves, without completing hand hygiene, and returned to the station and proceeded with cleaning of the dialysis station. 2. During observation day #2 on 6/01/22 observed: 	V 0113	<p>On or before June 25, 2022, the Clinic Manager will hold a staff meeting and reinforce the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> · Hand Hygiene <p>Education emphasis was placed on:</p> <ul style="list-style-type: none"> · Removal of soiled gloves and performing hand hygiene after direct contact with patient access and/or after contact with inanimate objects within the hemodialysis station. · Hand hygiene may be performed by hand washing or using an alcohol based hand rub. · Hand washing will include wetting hands, applying soap, rubbing hands vigorously, rinsing hands under running water and drying thoroughly with a disposable towel. Duration of the 	07/02/2022

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	<p>A. At 10:30 AM, PCT #3 in Station #7, with gloved hands, touch the patient's access dressing, then went to the hemodialysis monitor, then to the intravenous fluid bag, then without hand hygiene and glove change, he / she disconnected the first fistula needle (needle inserted into connection between an artery and a vein for dialysis access).</p> <p>B. At 11:20 AM, observed PCT #3 in Station #1 apply the facility supply of alcohol hand gel into their hands and rub hands for 5 seconds, then donned clean gloves and removed a dressing that covered patient's central venous catheter.</p> <p>C. At 11:25 AM, observed PCT #3 in Station #8 apply the facility supplied alcohol hand gel into hands and rub hands together for 5 seconds then donned gloves and connected sterile syringes to each central venous catheter (tube inserted into vein) port, artial and venous, (access site on central venous catheter to flush or withdraw solutions).</p> <p>D. At 11:30 AM, observed PCT #5 in Station #1 apply the facility supply of alcohol hand gel into hands and rub hands together for 8 seconds then don gloves and returned to the patient care area.</p> <p>3. During observation day #3 on 6/02/22 at 10:25 AM, observed PCT #6 at Station #4 to rub hand sanitizer in hands for 5 seconds prior to donning gloves. PCT #6 then touched the front of the hemodialysis machine.</p> <p>4. During an interview on 06/02/2022 at 4:10 PM, Clinical Nurse Manager indicated to complete hand hygiene with the facility provided alcohol hand gel was to rub the solution between all surfaces of the hands for 30 seconds and relayed</p>		<p>entire hand washing procedure will be 40-60 seconds.</p> <ul style="list-style-type: none"> Decontaminating hands with an alcohol based hand rub includes applying hand rub, rub hands together covering all surfaces of hands and fingers, allow to dry. Apply alcohol-based hand rub using the amount recommended by the product manufacturer. Duration of the entire hand rub decontaminating procedure will be per the product manufacturer's directions for use (DFU). <p>Effective June 27, 2022, the Clinic Manager or designee will conduct infection control audits daily for two weeks, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on practicing glove changes and hand hygiene per policy and product per manufacturer's DFU. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Clinical 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</p>	

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	<p>that hand hygiene and to don change of gloves was to be completed after touching any items in the dialysis station and before disconnecting a needle from a patient, after removal of blood lines, and hand sanitizer should be applied after removal of gloves.</p> <p>5. During observation day #4 on 6/03/22 at 12:47 PM, observed PCT #7 to depress the pump of a hand sanitizer, on the treatment floor, and rub hands together. Observed the staff member's hands were not visibly wet as PCT #7 rubbed their hands.</p> <p>6. During an interview on 6/03/22 at 12:55 PM, the Clinical Nurse Manager applied 3 light taps to the pump of a bottle of hand sanitizer, the solution was pumped into a clear plastic medication cup. The 3 light taps obtained 2.5 milliliters of hand sanitizer in the cup. The manager poured the solution into their hands and rubbed. The amount of solution [2.5 ml] was not sufficient to spread hand sanitizer over their entire hands.</p> <p>7. On 5/31/22 at 10:03 AM, observed PCT #1 touch their hair when they lowered their face shield. PCT #1 then donned a pair of gloves, without completing hand hygiene, and proceeded with patient care.</p> <p>8. On 5/31/22 at 11:17 AM, PCT #4 used his / her gloved hand to flip their hair back over their shoulder, then entered Station #6 to provide patient care. PCT #4 failed to complete hand hygiene after touching hair and before they entered Station #6 to provide patient care.</p> <p>9. On 6/1/2022 at 10:03 AM, PCT #1 touched their hair to lower the face shield, then donned gloves without completing hand hygiene.</p>		<p>the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>Documentation of education, monitoring, QAPI, and Governing Body is available for review.</p> <p>The Clinic Manager is responsible for overall compliance.</p>	

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	<p>10. During observation day # 3 on 6/2/22 it was observed,</p> <p>A. At 10:02 AM, PCT #1 with gloves in their hand. PCT #1 then scratched their head and then donned the gloves, without completing hand hygiene. Then PCT #1 was observed to use the computer in the dialysis station, then they removed the gloves, and completed hand hygiene for 4 seconds.</p> <p>B. At 10:05 AM, PCT #6 was observed completing hand hygiene and rubbing their hands together for 10 seconds before donning new gloves. At 10:06 AM, PCT #6 rubbed their hands together for 8 seconds, then picked up a thermometer, returned the thermometer to the counter, and then donned gloves without completing hand hygiene.</p> <p>C. At 10:08 AM, PCT #1 rubbed hands with alcohol hand gel for 6 seconds, then raised their face shield (touching their hair) and then donned gloves. PCT #1 then put their hands on their gown at hip level, then used the computer in the dialysis station.</p> <p>D. At 10:13 AM, PCT #5 was wearing gloves while providing patient care. PCT #5 then removed their gloves, rubbed hand with alcohol hand gel for 12 seconds, then donned gloves and removed the blood pressure cuff from the patient, then removed gloves and rubbed hands with alcohol hand gel for 8 seconds.</p> <p>E. At 10:30 AM, observed registered nurse [RN] manager touched their hair after completing hand hygiene and before they donned gloves. The RN was then observed to remove a needle and tubing (to circulate blood through the machine and the body) from patient and then touched the</p>			

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	<p>computer in the dialysis station without completing hand hygiene. The RN then rubbed their hands together for 9 seconds with alcohol hand gel, then took a patient's temperature, then donned gloves and began to touch the computer in the dialysis station.</p> <p>11. On 6/3/22 at 9:55 AM, observed that the hand sanitizer supply on the supply cart between station 7 and 8 was empty. RN #3 was observed to use the hand sanitizer and rub hands together, hands were not visibly wet. When RN #3 was queried about the empty bottle, RN #3 confirmed the supply did need to be replaced.</p> <p>12. During an interview on 6/3/2022 at 10:10 AM, RN# 3 and Patient Care Technician (PCT) #7 confirmed they did not know how much of the facility supply alcohol hand gel was to be used for effectiveness. PCT #7 indicated he/ she used 3 - 4 pumps. RN #3 indicated agreement by nodding their head. When queried, RN #3 indicated staff are to rub their hands together for 15 seconds while using the facility supply of alcohol hand gel.</p> <p>13. Review of a product information sheet, "ANIOSGEL 85 NPC," (retrieved from http://anios.com/ebola/ANIOSGEL%2085%20NPC-Fiche%20Technique-00000-EN.pdf) for the hand sanitizer found on the treatment floor. The instructions indicated the directions for use were to apply "... 3 mL [milliliters] minimum ... for 30 seconds"</p> <p>14. Review of an agency policy titled "Hand Hygiene" dated 11/04/2019, revealed hand hygiene was required "... Before and after direct contact with patients ... entering and leaving the treatment area ... immediately after removing gloves"</p>			

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V 0122 Bldg. 00	<p>15. Review of an agency document titled "Hand Hygiene Procedure" dated 9/26/2018, stated, " ... Step 2. Apply alcohol-based hand rub ... using the amount recommended by the product manufacturer ..." and " ... Rub hands together covering all surfaces of the hands and fingers until hands are dry"</p> <p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [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.</p> <p>Based on observation, record review, and interview, the facility failed to ensure staff stored the disinfectant solution, used in the treatment area to clean and decontaminate equipment, in a manner to prevent loss of the disinfectant properties and in accordance with facility policy in 3 of 4 treatment floor observation days [6/1/22, 6/2/22, and 6/3/22], creating the potential to affect all of the facility's 49 current incenter patients.</p> <p>Findings include:</p> <p>On 06/01/22 at 10:45 AM, observed PCT #3 pick up an infrared thermometer from a counter, in the treatment center, then took to Station #6 and while assessing patient's temperature, they touched the patient's hair when taking a forehead temperature and then returned the thermometer to the counter,</p>	V 0122	<p>On or before June 25, 2022, the Clinic Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> · Cleaning and Disinfection of the Dialysis Station <p>Education emphasis was placed on:</p> <ul style="list-style-type: none"> · Staff will ensure disinfectant solution, used in the treatment area to clean and decontaminate equipment, will be stored in a manner to prevent loss of the disinfectant. · Bleach solution will be stored in labeled, covered opaque containers to prevent 	07/02/2022

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	<p>without decontamination.</p> <p>On 06/01/2022 at 11:10 AM, observed the bleach solution, located on the counter in front of Station #7, was uncovered for more than 5 minutes.</p> <p>On 06/02/2022 at 9:35 AM, observed the bleach solution, located on the counter in front of Station #7 and Station #8 was uncovered for more than 5 minutes.</p> <p>Review of an agency policy titled "Cleaning and Disinfection of the Dialysis Station" dated 11/02/2021, indicated "... bleach solution will be stored in labeled, covered opaque containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air"</p> <p>During an interview on 06/02/2022 at 4:10 PM, Clinical Nurse Manager indicated the lid to the bleach solution would be off when staff remove bleach rags or when clamps are put in or taken out of the solution, otherwise the bleach solution is to remain covered and that the staff should decontaminate the thermometer with a cloth soaked in 1:100 bleach solution.</p> <p>On 6/1/2022 at 10:11 AM, PCT #3 used the infrared thermometer on Patient #15, touching the patient's hair while assessing patient's temperature. PCT #3 then returned the thermometer to the supply area without decontaminating the thermometer.</p> <p>On 6/1/2022 at 11:57 AM, PCT #4 used the infrared thermometer on a patient, touching the patient's forehead. PCT #4 returned the thermometer to the supply area without decontaminating the thermometer.</p>		<p>disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air.</p> <ul style="list-style-type: none"> · After use, all non - disposable equipment and supplies must be disinfected, including but not limited to thermometers. · Cleaning and disinfected all work surfaces within the hemodialysis station with 1:100 bleach solution after completion of procedures. <p>Effective June 27, 2022, the Clinic Manager or designee will conduct infection control audits daily for two weeks, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on disinfect storage and decontamination of non-disposable items per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Clinic 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 QAPI Committee monthly. The Director of Operations is responsible to present the status</p>	

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V 0715 Bldg. 00	<p>On 6/2/2022 at 9:44 AM, observed that a container labeled as 1:100 bleach solution, and used to disinfect clamps which were used during dialysis treatment, was left uncovered for more than 5 minutes.</p> <p>On 6/3/2022 at 12:45 PM, observed that a container labeled as 1:100 bleach solution, located by the hand wash sink, near stations 8 and 9, was left uncovered for more than 5 minutes. The solution was used throughout the day, after patient's dialysis treatment, to wet disposable cloths with bleach and then used to disinfect the dialysis machines and patient treatment chairs and equipment.</p> <p>Review of an agency policy titled "Cleaning and Disinfection of the Dialysis Station Procedure" dated 11/04/2019, stated, in part but not limited to, "... After use, all non - disposable equipment and supplies must be disinfected" The policy further stated "... Bleach solution will be stored ... covered ... containers to prevent disintegration of the chemical"</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P 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;</p> <p>Based on observation, record review, and interview, the medical director failed to ensure that policies and procedures were in place and followed to ensure expired supplies were not</p>		V 0715	<p>of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>Documentation of education, monitoring, QAPI, and Governing Body is available for review.</p> <p>The Clinic Manager is responsible for overall compliance.</p>	07/02/2022

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	<p>available for patient use and medication was secure in 1 of 1 facilities observed.</p> <p>Findings include:</p> <p>During the flash tour on 5/31/2022, the supply storage room was toured and observed one box of povidone- iodine prep pads, with an expiration date of 12/2021, and a case of JMS WingEater fistula needle sets that expired on 4/20/2022.</p> <p>On 5/31/22, during a tour of the supplies available on the treatment floor, twelve WingEather fistula needle sets, with an expiration date of 4/20/2022, were observed in the supply cabinet, by dialysis treatment station 12.</p> <p>During an tour of the lab room on 5/31/222, observed that supplies available for use included six expired red zebra lab tubes were in a drawer, in a box, labeled "Vacutainer Needles. One of the 6 tubes expired on 02/28/2022 and the other 5 tubes expired on 3/31/2022.</p> <p>During an observation of supplies on the treatment floor on 5/31/2022 at 2:45 PM, a small box of miscellaneous supplies were observed in the Supply drawer near Patient Stations #2 and #3. The box contained needles, alcohol pads, and several small yellow colored keys.</p> <p>Review of an agency policy titled "Storage of Supplies" dated 4/5/2021, stated, " ... Proper storage ... safe environment ... ensure supplies are not expired"</p> <p>Review of an agency policy titled "Medication Preparation and Administration" dated 5/2/2022, indicated the medication key and one spare key, would be kept in a secure location.</p>		<p>Governing Body By-Laws:</p> <ul style="list-style-type: none"> Medical Director Roles and Responsibilities Storage of Supplies Medication Preparation and Administration <p>Education emphasis was placed on:</p> <ul style="list-style-type: none"> Ensuring 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 non-physician providers. The Medical Director is responsible for the delivery of patient care in the Facility. Medical Director Responsibilities include, but are not limited to, the following: <ul style="list-style-type: none"> oversight of staff education, training, and performance. Review and approval with the policies and procedures. Oversight of all Medical Staff Members and their compliance with the Facility policies and procedures. Ensure policies and procedures are followed to remove expired supplies so they are not available for patient use, including but not limited to lab tubes, fistula needles, povidine-iodine prep pads, and vacutainer needles. Expired supplies will be immediately discarded per policy. 	

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	<p>During an interview on 5/31/2022 at 2:15 PM, the clinical manager confirmed expired supplies should not be on the treatment floor or in the storeroom.</p> <p>During a flash tour on 5/31/2022 at 9:40 AM, observed expired medical supplies in the supply room that included one bleach container with an expiration date of 4/27/22. In the emergency crash cart on the treatment floor, observed povidine-iodine prep pads (antiseptic cleanser to prevent skin infection) with expiration date of 4/2018 and in a supply drawer observed a bottle of hydrogen peroxide, with an expiration date of 5/2021.</p> <p>During a tour of the lab room, on 5/31/22 at 2:15 PM, observed ziploc bags labeled with patient names on the outside. Inside the bags were red top vacutainers (blood collection tube) with an expiration date of 8/2021.</p> <p>During an interview on 5/31/22 at 2:25 PM, the clinical nurse manager indicated the ziploc bags are prefilled for patient monthly lab draws and relayed the supplies would not be used until the supplies were reviewed for expiration dates.</p> <p>During an observation of treatment area on 6/02/22 at 10:15 AM, observed ziploc bag on top of the medication refrigerator and contained medication drawer keys.</p> <p>During an interview on 6/02/22 at 4:10 PM, clinical nurse manager indicated was not aware that staff were storing medication keys on top of the refrigerator and confirmed the keys opened the cabinets, including the medication drawers, and that the extra keys should be secured.</p>		<ul style="list-style-type: none"> Ensure medications are secure and extra keys to the medication storage cabinets will also be secure at all times. <p>Effective June 27, 2022, the Clinical Manager or designee will conduct supply storage audits daily for two weeks, then weekly for one month utilizing the Physical Environment Monitoring Tool. The focus will be on verifying supplies are utilized before expiration dates, prompt removal and replacement of expired supplies, and secure medication storage per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Clinical 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 QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152518	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 06/03/2022
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE WARSAW		STREET ADDRESS, CITY, STATE, ZIP COD 3334 LAKE CITY HWY WARSAW, IN 46580		
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V 0727 Bldg. 00	<p>494.170(a)</p> <p>MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL</p> <p>The dialysis facility must-</p> <p>(1) Safeguard patient records against loss, destruction, or unauthorized use; and</p> <p>(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:</p> <p>(i) The transfer of the patient to another facility.</p> <p>(ii) Certain exceptions provided for in the law.</p> <p>(iii) Provisions allowed under third party payment contracts.</p> <p>(iv) Approval by the patient.</p> <p>(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.</p> <p>Based on observation, interview, and record review, the facility failed to ensure the confidentiality of stored medical records during 1 of 4 observation days [5/31/22] with the potential to affect all of the 49 incenter Hemodialysis patients.</p>	V 0727	<p>provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>Documentation of education, monitoring, QAPI, and Governing Body is available for review.</p> <p>The Clinic Manager is responsible for overall compliance.</p>	07/02/2022

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	<p>Findings include:</p> <p>On 05/31/2022 at 2:35 PM, during a tour of the facility, observed an unlocked door; the door was to a room which contained the patient's paper medical records.</p> <p>During interview on 05/31/2022 at 3:30 PM, clinical nurse manager indicated the medical records room, which was near the secretary's office, was to be locked and relayed the secretary went home early today and did not realize the door to the medical records room was not secured.</p> <p>Review of an agency policy titled "Medical Record Guidelines" dated 03/20/2013, indicated "... all storage areas for medical records must be ... locked when personnel are not present"</p>		<ul style="list-style-type: none"> • All storage areas for medical records will be locked when personnel are not present. • Ensure the confidentiality of stored medical records. <p>Effective June 27, 2022, the Clinical Manager or designee will conduct medical record storage audits daily for two weeks, then weekly for one month utilizing the Physical Environment Monitoring Tool. The focus will be on verifying medical record storage areas are locked per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Clinical 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 QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions</p>	

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			<p>as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>The Clinic Manager is responsible for overall compliance.</p>	