

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

PRINTED: 07/06/2020

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152573	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  06/29/2020
--	---	--	---

NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE SALEM	STREET ADDRESS, CITY, STATE, ZIP COD 102 CONNIE AVE STE 104 SALEM, IN 47167
--	---

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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>This visit was for an Infection Control Focused Survey of a Dialysis Facility.</p> <p>Survey date: 6-29-2020</p> <p>Facility #: 002879</p> <p>Provider#: 152573</p> <p>Unduplicated Census:</p> <p style="padding-left: 40px;">In-Center Hemodialysis: 13</p> <p>At this Focused Infection Control Emergency Preparedness survey, in regards to staffing and implementation of staffing, Fresenius Medical Care, Salem was found to be in compliance with 42 CFR 494.62 Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers for this End Stage Renal Disease clinic.</p>	E 0000		
V 0000  Bldg. 00	<p>This visit was for an Infection Control Focused Survey of a Dialysis Facility.</p> <p>Survey date: 6-29-2020</p> <p>Facility #: 002879</p> <p>Provider#: 152573</p> <p>Unduplicated Census:</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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152573	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  06/29/2020
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE SALEM			STREET ADDRESS, CITY, STATE, ZIP COD 102 CONNIE AVE STE 104 SALEM, IN 47167		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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 0121 Bldg. 00	<p>In-Center Hemodialysis: 13</p> <p>QR Completed on 7/1/2020 A4</p> <p>494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [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- (i) Handling, storage and disposal of potentially infectious waste; Based on observation, interview, and record review, the facility failed to follow applicable standard infection control procedures &amp; policy in disposal of infectious waste for 1 (Patient #1) of 8 patients receiving dialysis treatments with the potential to impact all 13 of the Facility's patients.</p> <p>Findings include:</p> <p>Review of Facility's "Housekeeping Policy", with effective date of 3-20-2013, defined regulated waste as: ". . . contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed . . . microbiological wastes containing blood . . ." The policy further stated: ". . . All regulated waste shall be contained in red plastic bags or specially labeled cartons designed for regulated waste storage. Regulated waste must be kept separate from regular waste . . ."</p> <p>During Facility treatment floor observations on 6-29-2020 at 9:55 A.M., Employee C, a certified dialysis technician, was observed caring for a discontinued but bleeding arteriovenous fistula</p>	V 0121	<p>On or before July 7, 2020 all staff will receive reeducation on the expectations and responsibilities of the facility staff on proper disposal of contaminated, potentially infectious medical waste in accordance to FKC Policy FMS-CS-IC-II-155-116A - Housekeeping Policy Emphasis was placed on: To prevent cross contamination and to minimize the transmission of infections in the dialysis setting, contaminated items with blood and other potentially infectious materials will be appropriately placed and contained in red plastic bags or specially labeled cartons designed for regulated waste storage. Effective July 6, 2020, the Clinical Manager or designated Registered Nurse will conduct observational infection control audits, specific to</p>	07/07/2020	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152573	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  06/29/2020
--	---	--	---

NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE SALEM	STREET ADDRESS, CITY, STATE, ZIP COD 102 CONNIE AVE STE 104 SALEM, IN 47167
--	---

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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
	<p>site for Patient #1. The technician removed the blood soaked gauze and a 12" x 18" barrier chux (under pad), approximately 75% saturated with blood and disposed of the items in a clear bagged trash receptacle. Upon departure of Patient #1 and cleaning and disinfecting of station #4, the technician removed the said clear bagged waste containing the blood soaked items and placed it in a larger, holding container lined with a clear bag and used for standard trash rather than a red biohazard container.</p> <p>In an interview on 6-29-2020 at 10:01 A.M., the Facility's Clinical Manager stated blood soaked items, dialyzers, and lines are to be disposed of in the (large) red trash receptacle.</p> <p>During the exit interview on 6-29-2020 at 2:10 P.M., the Clinical Manager stated the technician acknowledged she did not dispose of the blood soaked items appropriately and realized it as soon as she had done it and that this would be corrected immediately. When queried, nothing further was provided.</p>		<p>disposal of medical waste daily x 2 weeks, then weekly x 2 weeks, then monthly x 2 months. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits as based on the QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>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 QAI 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 QAI 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, QAI, and Governing Body is available for review.</p> <p>The Clinic Manager is responsible</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152573	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  06/29/2020
--	---	--	---

NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE SALEM	STREET ADDRESS, CITY, STATE, ZIP COD 102 CONNIE AVE STE 104 SALEM, IN 47167
--	---

(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 0122 Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>[The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation, interview, and record review, the Facility failed to implement their written protocol and applicable infection control procedures for storing &amp; labeling of disinfectant solutions with the potential to impact all 13 patients on service.</p> <p>Findings include:</p> <p>Review of Facility policy, "Cleaning &amp; Disinfection of the Dialysis Station", last revised 7-1-2019, stated: ". . . 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>Review of Facility policy, "Mixing Bleach Procedure", last revised 3-20-2013, stated: ". . . 4. Label opaque container with "Bleach Solution",</p>	V 0122	<p>for overall compliance.</p> <p>On or before July 7, 2020 all staff will receive reeducation on the expectations and responsibilities of the facility staff on the proper mixing, storage and labeling of 1:100 and 1:10 Bleach Solution in accordance to FKC Policy and Procedure</p> <p>On June 30, 2020 the Clinical Manager clearly labeled the 1:100 and 1:10 Bleach Solution containers.</p> <p>On July 2, 2020 the Clinical Manager discarded the urinal being used to store 1:10 Bleach Solution and replaced it with a clearly labeled covered, opaque, container.</p> <p>Effective immediately and going forward, Bleach Solution will be stored in labeled, covered opaque</p>	07/07/2020

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152573	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED  06/29/2020
--	---	---	---

NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE SALEM	STREET ADDRESS, CITY, STATE, ZIP COD 102 CONNIE AVE STE 104 SALEM, IN 47167
--	---

(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
	<p>strength of solution, date and time prepared and your initials. 5. Cover opaque container with lid. ."</p> <p>During the tour of the Facility's dialysis treatment room on 6-29-2020 at 9:40 A.M., a cart containing cleaning items was examined. An opaque, fluid-filled container with a lid and date &amp; time of 6-29-2020 4 A.M. was identified on the top shelf of the cart. The container was labeled at the bottom with the faded word "Bleach". No other markings were found on the container.</p> <p>On 6-29-2020 at 10:05 A.M., when queried, the Clinical Manager initially stated the said receptacle, contained 1:10 bleach solution, and then quickly stated it was 1:100. When questioned again, the Clinical Manager confirmed it contained 1:100 bleach solution. During the same conversation, when queried regarding the location of the 1:10 solution, the Clinical Manager stated: "It was just here. We just used it." The Clinical Manager looked on the cart &amp; nearby cabinet, then provided a white, opaque, uncapped and empty, urinal (portable receptacle used by men when urinating) container and stated "We just used this and emptied it. It is our 1:10." Examination of empty urinal container, failed to evidence a label for contents (bleach), dilution, initials, and date &amp; time. Markings on one side of the container stated 1:10 and on the other side stated 1:100. When queried as to the strength of solution placed in the container, the Clinical confirmed it is used for 1:10 bleach solution.</p> <p>The Facility failed to implement its policy and follow infection control standards for mixing and storage of prepared disinfectants.</p> <p>On 6-29-2020 at 2:15 P.M., when queried, the</p>		<p>containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air. Bleach Solution containers will be labeled with "Bleach Solution", strength of solution, date and time prepared and your initials. FMS-CS-IC-II-155-110C5 - Mixing Bleach Procedure FMS-CS-IC-II-155-110A - Cleaning and Disinfection of the Dialysis Station</p> <p>Emphasis was placed on: Appropriate storage of 1:100 and 1:10 Bleach Solutions in opaque, covered containers with proper labeling to include "Bleach Solution", strength of solution, date, time and preparers' initials in accordance to FKC Policy and Procedure</p> <p>Effective July 6, 2020, the Clinical Manager or designated Registered Nurse will conduct observational audits of the mixed 1:100 and 1:10 bleach solution containers to ensure the solutions are stored in opaque, covered containers and that the containers are appropriately labeled with "Bleach Solution", strength of solution, date and time and preparers' initials daily x 2 weeks, weekly x 2 weeks, then monthly x 2 months. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on QAI calendar.</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152573	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  06/29/2020
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE SALEM			STREET ADDRESS, CITY, STATE, ZIP COD 102 CONNIE AVE STE 104 SALEM, IN 47167		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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	
	Facility Administrator and Clinical Manager provided nothing further.		The Medical Director will review the results of audits each month at the QAI 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 QAI 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 QAI 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. Documentation of education, monitoring, QAI, and Governing Body is availablefor review. The Clinic Manager is responsible for overall compliance.		