STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	432501	A. BUILDING _____ B. WING _____	C 08/07/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BLACK HILLS DIALYSIS - EAGLE BUTTE	201 S SYCAMORE ST POST OFFICE BOX 770 EAGLE BUTTE, SD 57625

(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 A complaint health survey for compliance with 42 CFR Part 405, Subpart U requirements for End Stage Renal Disease Services was conducted from 8/5/24 through 8/7/24. Areas surveyed included nursing services related to care plan development, dry weight determination, missed treatments, medication administration, medication orders reconciliation, HIPAA and confidentiality, chart scanning, and post-hospitalization review. Black Hills Dialysis - Eagle Butte was found not in compliance with the following requirements: V115, V143, and V360.	V 000		
V 115	IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK CFR(s): 494.30(a)(1)(i) Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. This STANDARD is not met as evidenced by: Based on observation, interview, and policy review, the provider failed to ensure personal protective equipment (PPE) was not worn outside of contact isolation rooms by two of two dialysis staff (F and G) for three of three (4, 5, and 6) sampled patients. Findings include: 1. Observation on 8/5/24 at 1:27 p.m. of patient 6, in contact isolation room 11 revealed patient care technician (PCT) F:	V 115	This Plan of Correction is to address the identified STANDARD not met during the survey from 08/05/2024 -08/07/2024 and will be implemented to correct V 115 IC-GOWNS, SHIELDS/MASK-NO STAFF EAT/DRINK CFR (s): 494.30 (a)(1)(i). All the patients at the facility had the potential to be affected by the STANDARD, V115, not met. 1. DON and Nurse Manager notified the Medical Director of the STANDARD not met upon the exit interview with the SD Department of Health Auditors on 8/7/24. 2. 08/08/24, 08/09/24, 08/10/24, 08/12/24, 08/13/24, DON and Nurse Manager notified staff verbally of the STANDARD not met regarding the wearing of contaminated gowns and gloves outside the isolation room. Removal of PPE will be completed in the isolation room and hand hygiene completed per protocol. Staff verbally informed that new PPE are to be put in place on transfer of patient out of isolation room. Staff will remove PPE per protocol complete hand hygiene on transfer from the isolation room. Facility wheelchairs will be cleaned per protocol. 3. 8/14/2024 DON sent an email to all staff again reviewing the STANDARD not met. The email directed the staff to review the Contact Precautions Policy that the Nurse Manager placed in a folder along with a signature sheet for all to sign once reviewed.	9/20/24

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Cindy H. Sinkey, RN	Director of Nursing/Acting Administrator	09/04/2024

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days 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 disclosable 14 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 115	Continued From page 1 *Exited the isolation room wearing his cloth protective cover gown, walked to the nurse's station, retrieved a pair of clean gloves, and returned to the patient's room. -Clean gloves were immediately accessible outside of the patient's room. Observation on 8/5/24 at 1:45 p.m. of PCT F with patient 6 revealed: *He removed his cloth protective cover gown and hung it on a hook inside the patient's room. *While wearing his contaminated gloves, exited the room pushing the patient in her wheelchair. *Wheeled the patient over to the scale, weighed her, removed his contaminated gloves, no hand hygiene was performed, and he then wrote the weight on a slip of paper. Interview on 8/5/24 at 1:51 p.m. with PCT F regarding patient 6 revealed: *She had finished her dialysis treatment. *She was not on isolation so "no need to change gown." *She had a history of bed bugs and was dialyzed in an isolation room. *The gown worn inside of the patient's room when providing patient care should not have been worn outside the room. *The gown hanging outside the patient's room was clean and should have been put on after leaving the room. *His contaminated gloves should have been removed prior to leaving the room and hand hygiene should have been performed. *PPE was worn to protect or contain any contamination. 2. Observation on 8/5/24 at 1:54 p.m. of certified clinical hemodialysis technician (CCHT) G	V 115	4. Nurse Manager will monitor Contact Precautions Policy adherence to ensure all staff have reviewed and acknowledged the policy. Any staff absent due to illness, vacation, or bereavement will be provided with education and the policy to review upon their return to work. 5. 8/26/24, DON discussed with the Medical Director regarding clarifying the Transport portion of the Contact Precautions Policy. Clarification to include new PPE to be donned after hand hygiene completed to take patient on contact precautions from isolation room to scale and then to waiting room. Updated policy to be reviewed and approved by Medical Director. 6. 8/27/2024, DON removed all hooks from inside isolation rooms. DON and Nurse Manager will review the STANDARD not met with staff members during staff meeting to discuss any further questions staff may have on corrective action. 7. Copy of updated Contact Precautions Policy to be provided to staff for review upon approval by Medical Director. Staff Audits will be collected by DON and or Nurse Manager 4 weeks. Ongoing education will be provided to staff to ensure all staff are donning and doffing PPE per protocol. ADDENDUM: by CS, 9/4/24 8. Skills training will be scheduled with staff members by DON or Designee to demonstrate hand hygiene, donning PPE before entering the patient's room/station for direct patient care, doffing PPE and hand hygiene to be completed before leaving the patient's room/station per Contact Precautions Policy. 9. DON or assigned Designee will conduct audits of all staff regarding the appropriate use of PPE following education and per policy. Audits will be random, but no less that 1-2 times weekly. DON will report results of audits during the quarterly QAPI and review results with the medical director on a monthly basis.	

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V 115	Continued From page 2	V 115		

revealed:
*While wearing her contaminated PPE, she pushed patient 4 in her wheelchair out of isolation room 12.
*She wheeled the patient to the front lobby, returned to the room, removed her PPE, and then performed hand hygiene.

Interview on 8/5/24 at 2:00 p.m. with CCHT G revealed she should have removed her contaminated gown and gloves, performed hand hygiene, and put on clean gloves prior to taking the patient to the lobby.

3. Observation and interview on 8/6/24 at 9:21 a.m. with registered nurse (RN) C of patient 5 revealed:
*A contact isolation sign was posted on her door.
*The patient had a diagnosis of methicillin resistant staphylococcus aureus (MRSA), an infection caused by bacteria that was resistant to many antibiotics.
*CCHT G placed a blood pressure cuff around the patient's right arm.
-She was not wearing a protective plastic gown over her scrubs.
*CCHT H was wearing PPE however the plastic gown was not tied in the back and flapped open when she moved or bent over.
*RN C confirmed:
-CCHT G should have worn a protective plastic gown over her scrubs to prevent contamination.
-CCHT H's protective cover gown should have been tied in the back for proper fit.

Interview on 8/6/24 with CCHT G immediately after the observation above confirmed:
*To prevent contamination of her scrubs she should have worn a protective plastic gown.

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V 115	Continued From page 3	V 115		

*PPE was used to keep herself safe.
*She was not sure why the patient was on isolation, she assumed "all [patients] on isolation and [were the] same level of care."
*Nurses inform staff how to care for patients on isolation when they are admitted, and an email with instructions was sent to staff on the patient's isolation status and care.
*She had access to the patients' charts and could have reviewed their isolation information.

Interview on 8/6/24 at 3:50 p.m. with director of nursing A revealed:
*For contact isolation staff wore plastic cover gowns and disposed of them prior to leaving the room.
*To prevent bacteria spread contaminated PPE should not have been worn outside contact isolation rooms.

4. Review of the provider's 9/19/16 Infection Control Guidelines revealed:
*"Every patient should be treated as if he/she is a potential carrier of infection."
*PPE should have been discarded before leaving the patient's station in the red biohazard container.
*"The gown must fully cover the arms and torso from the neck area to the thigh/knee area."
*The process of having a cloth protective cover gown inside contact isolation and one hanging outside the room was not addressed in the policy.

Review of the provider's 3/13/12 Infection Control Precautions for Contact Precautions revealed:
*Contact precautions were intended to prevent the spread of bacteria within the patient's environment.
*The patient was placed in a single-patient room

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V 115	Continued From page 4 or an isolation room when available. *When staff entered a contact isolation room: -Gloves were worn, changed after contact with infective material, removed before leaving the room, and then hand hygiene was performed. -Cover gowns were worn to protect staff clothing and were removed before leaving the patient's room. Review of the provider's 3/13/12 Hand-Washing Procedure policy revealed: *The purpose of the policy was to reduce the transmission of pathogenic microorganisms from patient to patient or patient to staff. *Dialysis patients may have areas of intact skin that might be colonized with MRSA. *Staff might contaminate "their hands with Klebsiella (bacteria) during a "clean" activity such as lifting a patient, taking a patient's pulse or blood pressure, or touching a patient's hand or shoulder." *"Hand antisepsis; refers to either antiseptic handwash or antiseptic hand rub." *Procedure: -Remove gloves if they are being worn. -Use soap and water if hands are visibly soiled. If not an alcohol-based hand rub may be used.	V 115		
V 143	IC-ASEPTIC TECHNIQUES FOR IV MEDS CFR(s): 494.30(b)(2) [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and	V 143	This Plan of Correction is to address the identified STANDARD not met during the survey from 08/05/2024 -08/07/2024 and will be implemented to correct V143 IC-ASEPTIC TECHNIQUES FOR IV MEDS CFR(s): 494.30(b)(2). All the patients at the facility had the potential to be affected by the STANDARD, V143, not met. 1. 8/5/2024, Expired medications noted during survey were removed from Medication cabinets in Medications room by Nurse Manager.	09/20/2024

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V 143	Continued From page 5 This STANDARD is not met as evidenced by: Based on observation, interview, policy review, and manufacturer's instructions for use (IFU) review, the provider failed to ensure: *Expired medications were not available for patient use. *Three of twenty-seven bottles of expired patient's medication were not available for patient use. *Medic anti-stick needle connectors (devices to reduce the risk of accidental needlesticks) had been used as a single dose device per manufacturer's IFU. Findings include: 1. Observation on 8/5/24 at 2:30 p.m. in the medication room revealed: *Twenty-five of twenty-five vials of gentamycin (antibiotic) 80 milligrams (mg) had expired May 2024. *Two of three bags of 50 milliliters (ml) of 0.9% normal saline had expired on 8/24/23. *A multi-dose bottle of benadryl 25 mg had expired on 7/24/24. *Three of twenty-seven bottles of patient's medication had expired. -One of four bottles of metoprolol (medication used to lower blood pressure) had expired on 5/7/24. -Two of twenty-one bottles of midodrine (medication used to increase blood pressure) 5 mg had expired July 2023. *Medic anti-stick needle devices had been used as a multi dose device to withdraw medication from vials into syringes to be used on multiple patients. Interview on 8/5/24 at 2:45 p.m. with registered nurse (RN) B revealed:	V 143	2. 8/7/24 DON and Nurse Manager notified the Medical Director of the STANDARD not met upon the exit interview with the SD Department of Health Auditors. 3. Medication list updated with expiration dates. IV and oral medications will be reviewed monthly by Charge Nurses no later than the last day of each month to ensure that expired medications are removed from stock and replaced. Replacement medications will be ordered by the Facility Manager for medications two weeks prior to their expiration date. 4. Medic anti-stick needle devices will be used per manufacturer's IFU. All registered nurses have been updated on the manufacturer's IFU for single use per syringe for pulling up medications. All registered nurses have read the IFU, acknowledged understanding, and signed the signature sheet. 5. DON and or Nurse manager will do weekly audits for 4 weeks. ADDENDUM: by CS, 9/4/2024 6. DON or Designee will audit Hand hygiene, medication preparation in designated area, disinfection of septum of vials, entering of vials with new Medic anti-stick needle and for each syringe per manufactures instructions. 7. Audits will be conducted at least 1-2 times weekly during the 4 week audit period. DON will report audit results as QA during the QAPI meeting and with the medical director on a monthly basis.	

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V 143	Continued From page 6	V 143		

*Expired medications in the cupboard had been available for patient use.
*Expiration dates on medications had been checked monthly.
*Patient's personal medications had been given as needed based on the patient's symptoms.
*There had been no formal process to check for expiration dates on patient's personal medication bottles.
-She stated, "The patients don't receive them very often."
*She would have expected staff to check expiration dates of medications prior to administration.
*She agreed the medications had expired and should not have been given to patients.
*Medic anti-stick needle connectors had been used to withdraw medication from vials into syringes for multiple patients.
*She stated staff used the connector up to five times to draw up medications into syringes before discarding depending on how many patients had been scheduled for dialysis.
*She was unaware if the connectors could have been used to draw up multiple doses of medication for multiple patients.

Interview on 8/6/24 at 1:10 p.m. with RN B revealed:
*Medic anti-stick needle connectors had been used to pull up heparin (blood thinner) into multiple syringes for administration to separate patients.
*A single medic anti-stick needle connector could have been used on one to five patients.

Interview on 8/6/24 at 2:13 p.m. with RN C revealed:
*She stated medication expiration dates had been

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V 143	Continued From page 7	V 143		

checked weekly.
*She would have expected staff to check expiration dates on medications prior to administration.
*There had been no formal process to check expiration dates on patient's personal medication bottles.
*She stated patient's personal medications had been rarely given to patients.
*When a patient's personal medications had expired; the pharmacy would have been called for replacement medications.
*Medic anti-stick needle connectors had been used to draw up heparin, sodium citrate (blood thinner), and lidocaine.
*She stated she would have drawn up multiple syringes with the same medic anti-stick needle connector and would have thrown it away when finished.
*She was unaware if the connectors could have been used multiple times.

Interview on 8/6/24 at 3:36 p.m. with director of nursing (DON) A revealed:
*Monthly checklists would have been completed to verify medication expiration dates.
*She would have expected staff to check expiration dates on medication prior to administration.
*Patient's personal medications had not been given often.
*There had been no formal process to check for expiration dates on patient's personal medication bottles.
*She agreed there should have been a formal process to ensure patient's personal medications were checked for expiration dates.
*Medic anti-stick needles had been used to draw up medications into multiple syringes and then

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V 143	Continued From page 8 discarded. *She was unsure if the connectors could have been used multiple times. Review of the provider's 6/27/13 Medication Administrative Policy revealed: *"Nursing staff must know the nature of the drug, the desired effect, the ordered dose, adverse reactions, expiration date, method of preparation and administration before the drug is given to a patient. *No medication will be kept beyond the expiration date even if it is only expired by one day. Promptly remove the medication and discard in a sharp's container. *If a medication is expired and must be discarded, record on the inventory log that the medication was expired, the date it was discarded, and the staff initials." Review of the manufacturer's October 2020 Medisystems Medic Anti-Stick Needle/Connector IFU revealed the device should have been for single use only.	V 143		
V 360	QA-GENERAL/RECORDS/TREND ANALYSIS CFR(s): 494.50(b)(1) 14 Quality assurance: general/records/trend analysis The criteria chosen as the internal standards of a facility shall be documented in its policy and/or procedure manual. Process review should be part of the activity of the individual carrying out the process, and oversight of that review by another qualified member of the staff or a group of staff members should affirm, modify, or repeat these observations to confirm or improve the process. Clinical outcomes serve as the most important	V 360	This Plan of Correction is to address the identified STANDARD not met during the survey from 08/05/2024 -08/07/2024 and will be implemented to correct V 360 QA-GENERAL/REOCRDS/TREND ANALYSIS CFR(s): 494.50(b)(1). 1. DON and Nurse Manager notified the Medical Director of the STANDARD not met upon the exit interview with the SD Department of Health Auditors on 8/7/24.	9/20/2024

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V 360	Continued From page 9 indicator of quality of all dialysis treatment practices including reuse. Final oversight is the responsibility of the medical director. See Table 2 for a summary of the audit schedule. 14.1 Records A record of review, comments, trend analysis, and conclusions arising from QA practices serve as a foundation for future review and as documentation to external evaluation. This STANDARD is not met as evidenced by: Based on record review, interview, and policy review, the provider failed to ensure: *Three of four sampled dialysis patients (1, 2, 4) who had missed or skipped treatments consecutively were called. *The reason for missing dialysis treatments had been documented in each patient's medical record. *Education had been provided to patients on the effects of missing treatments. Findings include: 1. Review of patient 1's medical record revealed: *On 7/25/24 staff had documented "Pt [patient] called stating not coming." *There was no additional documentation in the medical record to support the nurse had contacted the patient to inquire why that treatment had been missed. *There was no documentation to support education had been provided to the patient on the effects of missing treatments. 2. Review of patient 2's medical record revealed: *On 6/3/24, 6/8/24, 6/10/24, 6/12/24, 7/8/24, and 7/26/24 patient had been a no call/no show for her dialysis treatments.	V 360	2. 08/08/24, 08/09/24, 08/10/24, 08/12/24, 08/13/24, DON and Nurse Manager notified staff verbally of the STANDARD not met regarding additional documentation for contacting patients if they miss their treatment and any education that is provided. DON and Nurse Manager reviewed with staff that additional documentation can be included in Clarity in the Notes box next to the reason that is marked on their notation of Missed Treatment. Staff acknowledge that patients may decline to provide a reason. Education regarding documentation was provided to the staff. On the scheduled treatment day, the documentation will be included directly in Real Time Charting. If a patient notifies the facility prior to their treatment date that they will be missing their treatment, a Nurse or PCT Note will be generated. Education will be provided to the patient and the opportunity to reschedule hemodialysis treatment when needed. 3. 8/29/24 DON contacted IT with Clarity to enhance reporting data surrounding missed treatment and education provided. 4. DON will include this data in the quarterly Quality Assessment and Performance Improvement meeting to identify and address barriers to adherence. 5. Social Worker will meet with patients privately recurrent absences from dialysis treatments. Attempts will be made to identify barriers and create a comprehensive action plan with the patient to improve adherence and patient outcomes.	

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V 360	Continued From page 10 *There had been no documentation to support the patient had been called or the reasons why those treatments were missed or skipped. *There had been no documentation to support education had been provided to the patient on the effects of missing treatment. 3. Review of patient 4's medical record revealed: *On 7/22/24, 7/26/24, and 8/2/24, the patient had called and stated they were not coming to dialysis treatment. *There had been no documentation to support why treatments had been missed or skipped. *There had been no documentation to support education had been provided to the patient on the effects of missing treatment. 4. Interview on 8/7/24 at 11:12 a.m. with director of nursing A revealed she: *Would have expected staff to call patients if they had missed or skipped their dialysis treatments. *Would have expected staff to document a nursing note on reasons why patients had skipped or missed their dialysis treatments. *Stated, "Once we call or try to get a hold of them, that should be included in a narrative note." *Agreed documentation on patient education on the importance of dialysis treatments should have been provided and documented in a nursing note. 5. Review of the provider's revised February 2021 Missed/Skipped Treatment policy revealed: *"Educate patient on the effects of missing treatments on their overall health. *Reach out to patients to determine their reasons for missing/skipping treatments. *When patients are missing/skipping treatments consecutively, attempt to reach patients with courtesy calls to check on them.	V 360	ADDENDUM: by CS, 9/4/2024 6. Missed dialysis sessions will be extracted from the Missed Treatments Report created in Clarity. Social work team will review the data, patient education, and reasons for missed sessions from the documentation in Clarity monthly. 7. DON and Social work team will conduct monthly reviews of the Missed Treatments Report and share with staff monthly to identify barriers to patient adherence. 8. All patient interactions and action plans will be documented in Clarity as part of the patient plan of care. 9. DON and Social Worker will review the data monthly with the patient's providers and the Medical Director. Outcome data will be summarized for the quarterly QAPI meeting.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	432501	A. BUILDING _____ B. WING _____	C 08/07/2024

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V 360	Continued From page 11	V 360		

*If unable to reach patients directly try patient's emergency contacts and express concern.
*Document each step of this process in patients' Medical Record, including education provided and phone call attempts to reach patient."

6. Review of the provider's January, February, March 2024 Quality Assessment and Performance Improvement meeting minutes revealed the committee reviewed patient census statistics which included:
*Missed treatments.
*Shortened treatments.
*Treatments provided to the facility patients at other dialysis centers.
*An increase of 32 more missed treatments.
*There was no summary documented as to why the treatments had been missed or shortened, or why there had been an increase in missed treatments.

Interview on 8/7/24 at 12:51 p.m. with director of nursing A revealed:
*Patients would call in and state they were not coming or would not call and be considered a no show.
*Nursing staff were not consistent with contacting the patients and documenting why a patient had missed/skipped a treatment.
*Nursing staff were not consistent with documenting education provided to patients regarding the effects of missed/skipped dialysis treatments.
*A total of 105 dialysis treatments had been documented as missed on the January, February, March 2024 QAPI meeting minutes.
*To determine why the treatments were missed or shortened staff would have to manually review charts related to all 105 missed treatments and

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V 360	Continued From page 12 102 shortened treatments for the reason and education provided. *Having that information might be helpful for QAPI review to determine actions taken for resolution.	V 360		