STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	430016	A. BUILDING _____ B. WING _____	C 07/13/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
AVERA MCKENNAN HOSPITAL & UNIVERSITY HEALTH CENTER	1325 S CLIFF AVE POST OFFICE BOX 5045 SIOUX FALLS, SD 57117

(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
A 000	INITIAL COMMENTS	A 000		

A complaint health survey for compliance with 42 CFR Part 482, Subparts A-D; and Subsection 482.66 requirements for hospitals was conducted from 7/5/23 through 7/6/23 and on 7/13/23. Areas surveyed included patient rights, pharmaceutical services, and nursing services. Avera McKennan Hospital & University Health Center was found not in compliance with the following requirements: A115 and A489.

On 7/6/23 at 1:00 p.m. immediate jeopardy was identified related to patient rights at A115.
On 7/6/23 at 2:45 p.m. chief executive officer O, chief compliance officer C, quality director P, accreditation director D, senior director of medical support services K, risk manager B, and chief medical officer X were given verbal notice of the immediate jeopardy and were provided with the immediate jeopardy removal template.
On 7/12/23 at 1:30 p.m. the provider's immediate jeopard removal plan was accepted.
On 7/13/23 at 11:00 a.m. while onsite the removal plan was verified and immediate jeopardy was removed after the completion of document review, observations, policy review, and interviews.

On 7/6/23 at 1:00 p.m. immediate jeopardy was identified related to pharmaceutical services at A489.
On 7/6/23 at 2:45 p.m. chief executive officer O, chief compliance officer C, quality director P, accreditation director D, senior director of medical support services K, risk manager B, and chief medical officer X were given verbal notice of the immediate jeopardy and were provided with the immediate jeopardy removal template.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	President + CEO	8/29/23

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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A 000	Continued From page 1 On 7/12/23 at 1:30 p.m. the provider's immediate jeopard removal plan was accepted. On 7/13/23 at 11:00 a.m. while onsite the removal plan was verified and immediate jeopardy was removed after the completion of document reviews, observations, policy review, and interviews. The patient census was 288.	A 000	Avera McKennan's Follow up actions are as follows: a. Human Resource started an investigation immediately. Patient Care Technician was suspended from work until investigation was completed b. Further investigation was done by Human Resources, interview of the Patient Care Technician, Unit Supervisor, Registered Nurse assigned to the patient, and Resource Nurse. c.Human Resource's investigation completed. Human Resources concluded this was an isolated incident and the employee was cleared to return to work. Appropriate education was provided to the Patient Care Technician by both the Resource nurse and the Registered nurse caring for the patient, announcing himself upon entering the room and asking the patient for permission prior to providing personal cares. 2. Avera McKennan's Follow up actions are as follows: a. Education was created i. Review of the Policy for Adult Protective Service Reporting ii. Patient Perception iii. Staff Expectation iv. Incident Reporting Process v. Who to contact if a situation occurs b. Education roll out	8.22.23
A 115	PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on a review of the South Dakota Department of Health complaint intake information, record review, interview, and policy review, the provider failed to ensure an investigation had been conducted for one of one sampled patient (1) who had been "violated" by one of one patient care technician (PCT) Y. Findings include: This failure has the potential to cause harm to other patients since no investigation had been conducted. Notice: On 7/6/23 at 2:45 p.m. the facility chief executive officer O was informed of an Immediate Jeopardy (IJ) for failure to conduct an investigation to ensure that this was an isolated incident. Plan: The facility provided the following acceptable removal plan on 7/12/23 at 1:30 p.m. for patient	A 115	i. Education reviewed with Supervisors for Brain and Spine Unit first. ii. Education reviewed with All Leaders, including Nursing Leaders, Pharmacy Leaders, Supervisors, and Nurse Educators for All units. iii. Education then created online for all employees to review and sign. Completion of education will be required and reviewed by leaders of every area. 1. Leaders from the nursing units will monitor, verify, and require that all staff is educated prior to their shift. 2. PRN staff will be contacted and mandated to complete education prior to their next shift. iv. Quality will receive a copy of the signed education, as well as the Healthstream tracker to verify education is completed by all staff through unit leaders daily. A report then given to the CNO daily. 3. Further steps: a. Medical Support Services plan to also provide immediate jeopardy items to the Avera McKennan Quality Committee. i. Quality Committee will then review and give further approval of action plan. ii. Follow up will be reported out to the Quality Committee with the roll-up to the Board of Trustees	

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A 115	Continued From page 2 rights: 1. "Human resources has started an investigation as of Thursday 7.6.23 at 4:30 p.m. patient care technician was suspended from work until the investigation was completed." 2. "Further investigation was done by human resources between 7.7.23 and 7.10.23, interviews with patient care technician, unit supervisors, registered nurse assigned to the patient, and the resource nurse." 3. "As of 7.10.23 at 3:00 p.m. human resource's investigation is complete. Human resources concluded this was an isolated incident and the employee was cleared to return to work. Appropriate education was provided to the patient care technician by both the resource nurse and the registered nurse caring for the patient, announcing himself upon entering the room and ask the patient permission prior to providing personal cares." 4. Education was created, 7.10.23: a. "Review of the policy for adult protective service reporting." b. "Patient perception." c. "Staff expectation." d. "Incident reporting process." e. "Who to contact if a situation occurs." 5. Education has been rolled out 7.11.23 at 1:00 p.m.: a. "Education reviewed with supervisors for the brain and spine unit 7.11.23 at 1:00 p.m." b. "Education reviewed with all leads, including nurse leaders, pharmacy leaders, supervisors, and nurse educators for all units 7.12.23 at 9:00 a.m." c. "Education will then be created online for all employees to review and sign by 7.12.23 Completion of education will be required and reviewed by leaders of every area."	A 115	Leaders on the units monitor, verify, and require that staff is educated. Education is currently at 95.42%. Leaders continue to follow up with staff by reaching out to them if they are on FMLA, vacation, or any other type of leave to make sure they are aware to complete prior to their next shift. Nurse leaders continue to educate those employees by using the paper form. Education for new staff is discussed by our Director of Risk, Quality and Patient Experience in person, then also must complete online education by 30 days of employment. This is maintained by the leader of the unit and Human Resources. Quality continues to educate employees on patient rights at unit meetings and answer questions and concerns daily from the units. Also updating the yearly education with the Avera education center to reflect additional information and importance of patient rights and perceptions Quality Committee made aware of IJ and is updated at each meeting of the education process and completetion rate.	8.22.23

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A 115	Continued From page 3	A 115		

1. "Leaders from the nursing units will monitor, verify, and require that all staff is educated prior to their shift."
2. "Prn staff will be contacted and mandated to complete education prior to their next shift."
d. "Quality will receive a copy of the signed education, as well as the Healthstream tracker to verify education is completed by all staff through unit leaders daily starting 7.11.23 A report will then be given to the CNO daily."
6. "Medical support services plan to also provide immediate jeopardy items to the quality committee."
a. "Quality committee will then review and give further approval of action plan."
b. "Follow up will be reported out to the quality committee with the roll-up to the board of trustees."

The removal plan for the IJ was received and accepted on 7/12/23 at 1:30 p.m. On 7/13/23 at 11:00 a.m. the implementation of their plan was verified and their IJ status was removed while the surveyors were onsite.

Findings include:

Review of the South Dakota Department of Health complaint intake information revealed:
*Patient 1 had been diagnosed with cerebral palsy and had a spinal cord injury which required the use of a wheelchair for mobility.
*Patient 1 had been sleeping and PCT Y began performing his catheter care.
*PCT Y had been asked multiple times by patient 1 to stop with his cares once he woke up.
*PCT Y finally stopped and exited the room.
*Patient 1 reported to registered nurse (RN) S that PCT Y had touched him inappropriately and

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PCT Y was not allowed to care for him anymore.
*PCT Y had been reassigned to another patient care area on that floor.
*Patient 1 had been sexually abused in the past by a male and would have preferred female staff whenever possible to perform cares.
*Patient 1 had thought about leaving the hospital against medical advice (AMA) because he had not felt safe.

Review of patient 1's electronic medical record (EMR) revealed:
*He had been admitted on 6/3/23 with a diagnosis of failure to thrive.
*On 6/28/23 at 10:28 p.m. licensed practical nurse (LPN) V had noticed that patient 1 had been gone from the unit for several hours.
*On 6/28/23 at 10:30 p.m. RN U noticed that patient 1's belonging had been removed from his room.
-She contacted security and they reviewed the video cameras.
-Patient 1 had been seen on the camera with his service dog, belongings, and a female visitor leaving AMA from the hospital on 6/28/23 at 5:11 p.m.

Interview on 7/5/23 at 2:15 p.m. with RN Q and RN W regarding training provided to PCTs revealed:
*Hospital wide training for new employees had been conducted by human resources.
-Hospital wide training included patient rights and abuse/neglect among other areas.
-PCT Y had been hired in April 2023.
*PCTs would have received more on the job training on their designated unit.
-On the unit training would have been completed differently with PCTs that had more experience.

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A 115	Continued From page 5	A 115		

*PCTs were expected to have reported any suspected abuse or neglect to the nurse.
*The nurse would have reported any suspected abuse or neglect to the resource nurse and then that information would have been reported to the nurse supervisor.
*RN Q would have interviewed the patient and PCT to obtain further information regarding the allegation of sexual abuse.

Review of staff education for RN Q and PCT Y revealed they both had completed training on patient rights and abuse/neglect in May 2023.

Interview on 7/6/23 at 8:35 a.m. with RN Q regarding reported alleged sexual assault to patient 1 revealed:
*RN S had informed her that patient 1 had felt violated by PCT Y and that PCT Y had been reassigned to another area on the unit.
*She had asked RN S if patient 1 accused PCT Y of any sexual abuse.
-RN S stated patient 1 had felt violated by PCT Y.
*She had been aware that patient 1 had a history of sexual abuse by a male.
*She had monitored the situation but had not informed her supervisor or risk management of patient 1's feelings.
*She thought that a patient feeling violated was not serious enough to report to her supervisor or risk management.

Interview on 7/6/23 at 9:00 a.m. with RN K regarding patient 1 feeling violated by PCT Y revealed:
*Information that had been obtained by a staff member should have been reported to the supervisor and to risk management.
*Patients that had a history of sexual abuse, that

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A 115	Continued From page 6	A 115		

information should have been in their chart as personal health information for staff to have been made aware.

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Interview on 7/6/23 at 10:00 a.m. with patient care leader R regarding the above information from the complaint intake information and the interview with RN Q revealed:
*He had not been informed of patient 1 feeling violated by PCT Y.
*He had been the lead for that unit since June 2023 but had previously been a lead in the emergency room.
*He expected RN Q to inform him, the patient care representative, and risk management of patient 1 feeling violated.
*PCT Y should have been removed from performing patient care pending the outcome of an investigation.

Review of the provider's September 2021 Patient/Family Complaints and Advocacy Policy revealed:
*The policy establishes a procedure for channeling patient care related to complaints.
*Complaints were recorded in a database maintained by the patient representative coordinator.
-Complaints, concerns, or requests for assistance were channeled to the appropriate department, director/manager for investigation and a resolution.
*Complaints were given proper consideration as a risk management issue.

Review of the provider's April 2023 Corrective Action policy revealed:
*Examples of when an employee should have been suspended pending a human resource

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A 115	Continued From page 7 investigation included, but were not limited to the following: -A situation that involved allegations of abuse by an employee. -A situation where the employee needed to have been removed to conduct a thorough investigation.	A 115	Action Plan 1. Turn on Blind Counts (this is a pyxis setting where all users, that pull the medication, physically count the contents of the pocket prior to medication removal) for Propofol in the Pyxis. a. Notification will be sent via Voalte, Email and Daily Lineup, about new process. i. Pharmacy will send to the Patient Care Leaders, Certified Nurse Educators, Supervisors, and Pharmacy staff. 2. Change waste requirement of propofol to pyxis (like narcotics process) on medical units with destruction in CSRX bottle. a. Inform staff of the change in waste of propofol. b. Voalte message will be sent, Daily lineup, Friday updates by Managers, Email, and Quality Boards. c. Labels will be made and attached to the CSRX bottle to include Propofol. 3. Run list for Pyxis Medications pulled without a corresponding admin for high-risk diversion medications. a. Report validation completed. b. Pharmacy will contact Leader with the report. After the leader reviews report, they then can move forward with investigation of the lack of documentation of administration. If the employee is unable to explain and show documentation of rate via the IV flowsheet. Corrective action and continued monitoring will be set for the individual employee with all future occurrences of administration. c. Report will be will sent to the nurse leaders daily for 3 months, until 10.12.23 and revisit to continue to evaluate documentation and administration. 4. Drug Diversion Investigation Response Team (DDIRT) – we recognize that medications are a patient safety and employee safety issue. DDIRT is a component of our Patient Safety process to deliver and understand an individual's performance within our institution as it relates to substance abuse or medication diversion as directed by the Regional Controlled Substance Oversight Committee. It is an investigative arm to the Regional Controlled Substance Oversight Committee. a. DDIRT meets on an ad hoc basis to review specific instances of potential medication diversion – Activated by anyone that has a concern of a diversion, leaders, as well as surveillance tools. b. Education to all leaders involved in distribution and administration of medications. i. Education has been rolled out to staff at every shift as well as on Healthstream, to complete prior to their shift beginning. c. Meetings and Minutes will include action plan and follow up plan. d. Report out to Regional Controlled Substance Oversight Committee meeting, Patient Safety and Pharmacy and Therapeutics – Quarterly. e. Risk Management report out to Avera McKennan Quality Committee and Patient Care Leaders.	8.22.23
A 489	Condition of Participation: Pharmaceutical Se CFR(s): 482.25 §482.25 Condition of Participation: Pharmaceutical Services. The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. This CONDITION is not met as evidenced by: Based on a review of the South Dakota Department of Health (SD DOH) complaint intake information, observation, interview, job description review, and policy review, the provider failed to ensure pharmacy services implemented a security process following the misappropriation of use for both controlled and non-controlled medications in one of one intensive care unit (ICU) by one of one registered nurse (RN) (A). These failures have the potential for misappropriation of medications to continue since no processes or policies had been changed.	A 489		

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A 489	Continued From page 8 NOTICE: On 7/6/23 at 2:45 p.m. facility chief executive officer O was informed of an Immediate Jeopardy (IJ) for failure to ensure a security process had been implemented and updated following a drug diversion of four bags of Fentanyl and twelve bottles of Propofol. PLAN: The facility provided the following acceptable removal plan on 7/12/23 at 1:30 p.m. for pharmaceutical services: 1. "Turn on Blind Counts (this is a pyxis setting where all users, that pull the medication, physically count the contents of the pocket prior to medication removal) for Propofol in the Pyxis 7.12.23 @ [at] 0800 [8:00 a.m.]. *Notification will be sent via Voalte, Email and Daily Lineup, on 7.11.23 about new process. *Pharmacy will send to the Patient Care Leaders, Certified Nurse Educators, Supervisors, and Pharmacy staff." 2. "Change waste requirement of propofol to pyxis (like narcotics process) on medical units with destruction in CSRX [Stericycle's medication waste container]." *Inform staff of the change in waste of propofol, 7.11.23. *Voalte message will be sent, Daily lineup, Friday updates by Managers, Email, and Quality Boards. *Labels will be made and attached to the CSRX bottle to include Propofol, completed 7.10.23." 3. "Run list of Pyxis Medications pulled without a corresponding admin for high-risk diversion medications. *Report validation to occur this week, complete	A 489	Continue to run list for pyxis medication pulled without a corresponding administration for high-risk medication daily for 90 days. Pharmacy contacts the leader with the report. After the leader reviews the report, a decision is made to move forward if necessary. If the employee is unable to explain and show documentation of rate via the IV flowsheet, corrective action and a full investigation is continued. The DDIRT team will then move forward with the investigation. The report will be sent to the leaders daily M-F for 90 days. After that point, we will revisit to continue or look at a new process. Weekend report run and reviewed Monday morning after the weekend. Discrepancies and audits reported to the Quality Committee quarterly as consent agenda items and Regional Controlled Substance Committee quarterly by the Director of Quality, Risk, and Patient Experience, on going Suspected/potential diversion or significant loss of controlled substance process: Can be reported through variety of methods 1. Individual suspicion of colleague/co-worker 2. Self-reporting 3. Anonymous report 4. Changes in work quality or frequency noted by others 5. Data anomalies detected by regular data review or noted through other mechanisms 6. Other Once reported to any member of the Quality/Risk or Pharmacy teams, the Chair/Moderator of the DDIRT team is notified Chair/Moderator confers with appropriate leadership (nursing, pharmacy, risk management, HR, or others as dictated by situation) and schedules initial meeting of the committee as indicated. Invitees include the available members of the core DDIRT team as identified in policy plus additional personnel/leaders as necessary to initiate an investigation. At first meeting, the DDIRT team reviews initial information and determines specific review and investigation to occur. Minutes are kept at all meetings and are maintained separately from case file specific information. Subsequent investigative work and meetings are scheduled as needed. Reorganization and Revamp of the Drug Diversion Team - DDIRT team will be chaired by a neutral party with experience in Pharmacy and compliance matters. - This person will initiate the DDIRT meeting after becoming aware of an issue/suspicion. - Once DDIRT team is initiated. Risk will place a DOH report under suspicion DDIRT meeting - There will be an agenda for each meeting - There will be minutes kept for each meeting o This will include the case number - The case information will be stored outside of the minutes in a Case Folder o To include all documents of the investigation - If team concludes a full investigation is needed o DDIRT team to do internal investigation to conclude there is legitimate suspicion or cannot be ruled out - Appropriate entities notified *Pharmacy contact DEA *Pharmacy contacts Board of Pharmacy - 106 form *Risk Management contacts DCI *Risk Mangement reports to licensing firm - Investigation complete - Risk to finalize formal DOH report from suspicion to submitted	8 22 23

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A 489	Continued From page 9 7.12.23. *Pharmacy will contact Leader with the report. After the leader reviews report, they then can move forward with investigation of the lack of documentation of administration. If the employee is unable to explain and show documentation of rate via the I [intravenous flowsheet. Corrective action and continued monitoring will be set for the the individual employee with all future occurrences of administration. *Report will be sent to the nurse leaders daily for 3 months and revisit to continue to evaluate documentation and administration. *Implementation to begin 7.12.23." 4. "Drug Diversion Investigation Response Team (DDIRT) - we recognize that medications are a patient safety and employee safety issue. DDIRT is a component of our Patient Safety process to deliver and understand an individual's performance within our institution as it relates to substance abuse or medication diversion as directed by the Regional Controlled Substance Oversight Committee. It is an investigative arm to the Regional Controlled Substance Oversight Committee. * DDIRT meets on an ad hoc [as needed] basis to review specific instances of potential medication diversion - Activated by anyone that has a concern of a diversion, leaders, as well as surveillance tools. *Education to all leaders involved in distribution and administration of medications @ 7.11.23 @ 0900 [9:00 a.m.]. -Education has been rolled out, 7.12.23, to staff at every shift as well as on Healthstream, 7.12.23, to complete prior to their shift beginning. *Meetings and Minutes will include action plan and follow up plan.	A 489	Proactive monitoring - Pharmacy Technology Team - Review for any significant discrepancies or data anomalies Daily, M-F - Discrepancy and documentation review with inpatient nursing leaders - daily - Control Check, currently, with a diversion monitoring/detection tool Daily M-F. Weekend report run on Monday morning for review of weekend administrations. - Continue manual daily control checks until Improvements/upgrades, due in early 2024 - If Discrepancy is unable to be resolved or suspicion of diversion is identified, reported to Control Substance Coordinator, Chair of DDIRT team, Risk Manager, Pharmacy Leader, or Compliance Hotline - Discrepancies and audits reported to the Quality Committee quarterly as consent agenda items and Regional Controlled Substance Committee quarterly, by the Director of Quality, Risk and Patient Experience, on going Regional Controlled Substance Committee - Meet Quarterly - DDIRT agenda and minutes to become a consent agenda item - DDIRT action/correction items to be discussed at meeting - Audit reports, discrepancies, as well as diversion investigations	8.22.23

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*Report out to Regional controlled Substance Oversight Committee meeting, Patient Safety and Pharmacy and Therapeutics-Quarterly.
*Risk Management report out to Avera McKennan Quality Committee and Patient Care Leaders."

The removal plan for the IJ was received and accepted on 7/12/23 at 1:30 p.m. On 7/13/23 at 11:00 a.m. the implementation of their plan was verified and the Immediate Jeopardy status was removed while the surveyors were onsite.

Findings include:

1. Review of the provider's 6/14/23 final incident report investigation submitted to the SD DOH on suspicion of misappropriation of meds by RN A for both controlled and non-controlled meds revealed:
*The report was submitted to the SD DOH 14 days after the identification and suspicion of the drug diversion had occurred.
-An initial report should have been submitted to the SD DOH within 24 hours of the identification of the suspicion of drug diversion.
*He had been employed with the facility since 9/6/20.
*A co-worker had brought forward a report suspecting him of diverting (stealing) drugs.
*An investigation was opened on RN A for a possible drug diversion.
*RN A:
-Required disciplinary action and he was terminated on 5/31/23 for reasonable suspicion of drug diversion that occurred from 2/4/23 through 4/24/23.
-Admitted to poor and sloppy documentation, but had not admitted to diverting any drugs.
*Through the provider's investigation the following

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list of meds had been unaccounted for:
-Fentanyl (pain medication) 4 bags. There was no documentation to support the dosage of the med nor the milliliters (ml) in the bags.
-Propofol (anesthetic used for sedation) 12 bottles [vials]. There was no documentation to support the size and amount of medication that was in those vials.
*"Through the investigation, we do not believe any patients were harmed as a result of this employees activities."
-There was no documentation to support how the investigation had been completed to support no harm to the patients had occurred.
*The abuse/neglect allegation for RN A was not substantiated since he had not admitted to the diversion of those meds.
*The action taken by the provider to ensure a drug diversion of that magnitude would not occur again was to terminate RN A.
*There was no documentation to support the following:
-Facility procedures and processes for drug security had been reviewed or revised to ensure the diversion of meds would not occur again.
-Personnel education or re-education on the current or revised policies for med security had been completed.

Observation and interview on 7/6/23 at 8:10 a.m. with RN D, RN G, and pharmacist H in the medication dispensing and wasting area of the emergency department (ED) revealed:
*The room was large and had several unidentified staff members working in the room on computers and various other activities.
*Some of those areas and staff were located approximately 5 feet (ft) from the Pyxis (automated medication dispensing machine) and

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A 489	Continued From page 12 biohazard waste containers. *There were three biohazard waste containers located right next to the Pyxis. -The containers were approximately 2 ft tall with large openings on the top of them. The lids attached to the openings could have been opened manually or with a foot-activated device. The opening was large enough to put a hand inside of it. -Inside those containers were multiple vials, intravenous tubing (IV), and syringes. -Those containers were used for wasting non-controlled meds that had not require 2 people for wasting meds. *One of the containers was 3/4 full and had a small syringe laying on top of the contents. -It was 3/4 full of a white liquid substance and was labeled Propofol. *The contents inside of the vials, syringes, and the tubing were not required to have been wasted prior to placing them into the containers because they were non-controlled meds. *They agreed some of the meds could have had a negative outcome should they have been handled inappropriately. *They were not aware of any recent education or process changes for the security of meds and drug diversion. -Stated: "Not anything outside of our yearly mandatory training on that which we just had to complete." *The pharmacist stated: -"Those meds are non-controlled and don't need a witness for wasting." -"Propofol is not a controlled substance so therefore, does not require a witness for wasting and can be put in that container." -"I'm not aware if Propofol is a highly diverted or high-risk med or not."	A 489		8 22 23

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A 489	Continued From page 13 -"Controlled substances require two people to waste and we do that in the SteriCycle container over there on the wall." *The staff had the capability to override the system in emergency situations when the physician had not entered an order in the system for a STAT (immediately) med. *If a staff member was not available to waste a controlled substance the system would leave it open and incomplete. -Per the pharmacist, those were reviewed for appropriateness. *The surveyor requested the provider's policy on the process for med destruction and accountability for non-controlled substances. Observation and interview on 7/6/23 at 8:45 a.m. with RNs G and I in the medication dispensing and wasting area for the Pediatric Intensive Care Unit (PICU) revealed: *We entered an unsecured room where the Pyxis machine and the biohazard medication waste containers were located. -The room was clean and contained multiple patient use items. -Housekeeping, maintenance, and all staff had access to the room. -Housekeeping and maintenance would have removed the biohazard waste containers after they were full. *RN I confirmed all controlled substances required: -A second person for wasting the meds into the SteriCyle biohazard waste container. -The staff would complete a count upon the removal of any medication and prior to closing and locking the Pyxis. -All non-controlled meds should have been placed in the two large biohazard containers	A 489		

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A 489	Continued From page 14 sitting on the floor next to the Pyxis. *Propofol was used in the PICU for conscious sedation prior to any procedures. *One of the large biohazard waste containers: -Was full of vials, syringes, and IV tubing. All of them had some type of medication left in them. -Had a 30 cubic centimeter (cc) syringe 1/2 full of a white substance and was labeled Propofol. -Had multiple IV tubing in it and were full of a white substance. RN I confirmed the substance would have been Propofol. *RN I: -Confirmed that Propofol was a high-risk medication due to its mind-altering affects. -Was aware that Propofol was a highly diverted med. -Agreed all meds should have been accounted for from the time they enter the facility to when they are utilized by the patient. -Stated: --"It's not controlled so we just put it in that large bin. We don't have to waste it and we just throw it and other meds in those bins." --"Yep, anyone can reach in that bin and take what they want." -Agreed that housekeeping and maintenance were not considered authorized staff to have been handling wasted medication. *She was the lead supervisor for the area and any medication discrepancies were given to her for review and follow-up. *There recently was a discrepancy with a controlled substance that was created by a nurse. *RN I stated: -"The nurse had entered the wrong number after she did a count of what was left in the Pyxis." -"Instead of correcting it or reporting it to the supervisor, she just did an override on it." -"The system will let you know there is a	A 489		

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discrepancy, but you can override it and that's what she did."
-"Two other staff came behind her and the system showed an error, they entered the right count, but just did an override and kept working."
-"It was two nurses deep into the discrepancy before it was caught."
-"Not sure what the process for review on that would be. We just get handed the reports to figure out what happened."
-"The nurse should have either gotten a supervisor to help or reported it if she couldn't fix it at that time."
-"No, we have not had any changes in processes for med security and diversion that I'm aware of."
-"No, no education on anything like that recently, nothing extra outside of our mandatory training. We did recently have to do that."
-"As the supervisor I would have known and helped with any educating."

Interview on 7/5/23 at 2:40 p.m. with pharmacist E revealed he:
*Was the pharmacy manager for inpatients and assisted the pharmacy director in his absence.
-The pharmacy director was currently on vacation.
*Confirmed the observed processes above for both the controlled and non-controlled meds for wasting and accountability.
*Was not aware of any drug diversion concerns recently and typically would not have been involved with them.
*Would have pulled reports when asked to help with the review, but otherwise, no involvement with that process.
*Stated:
-"My role is specifically within the pharmacy. If there is an issue with drug diversion or

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accountability, the unit leaders would handle that."
-"I do not work directly with the nursing staff, the unit leaders do that."
-"We have a controlled substance coordinator and she would take the lead on any changes there."
-"[Controlled substance coordinator's name] and the pharmacy director work together on the drug diversion issues."
-"I'm not aware of any recent drug security concerns and usually I don't know. I'm not privy [privileged] to that information."
-"I don't know of any process changes for med security or recent education on changes."
-"We do have a drug diversion investigation response team (DDIRT) and the controlled substance coordinator J takes the lead on that."
-"There have been discussions on treating Propofol as a controlled substance, but that's all I know, so I can't speak to any process changes specifically for that."
-"Propofol is not considered a high alert or high-risk med. All meds have the capability of having a negative outcome if handled inappropriately. It's not controlled so it's not monitored as closely."
*Frequently deferred his answers to check with the controlled substance coordinator on med security processes for both the controlled and non-controlled substances.
*Confirmed that the Pyxis system had an override capability but should have been used in emergent cases only.
*Discrepancy audits would have been completed on a daily basis.

Interview on 7/6/23 at 9:25 a.m. with controlled substance coordinator J revealed:

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*She confirmed:
-She and the pharmacy director took the lead on drug diversion reviews for the DDIRT and made recommendations for any required changes from those reviews.
-The staff had the capability to override the system, but in emergent situations only. To her knowledge that was the only time it was or should have been used.
-There had been a recent drug diversion investigation on the intensive care unit.
*She stated:
-"It was a hard diversion to review, he didn't document administrations, or end times, his scanning rate was 62% and should have been 95% or greater."
-"We reviewed 29 charts on patients that he cared for and had orders for Fentanyl or Propofol."
-"His documentation was so poor that I had to have pharmacy help look at drip times to tell when the bags ended. Then we could see when he should have started a new bag."
-"The Fentanyl was easier to track because it's a controlled substance but Propofol isn't and there's no blind count [required count upon removal of the med from the system]."
-"Propofol is not a controlled substance so technically we don't have to monitor that one closely."
-"We increased our auditing for staff scanning, but we were doing that before this happened. They should scan the med with administration. He was not doing that or documenting administrations."
-"No there was nothing changed or re-education on med diversion because we just had it in May."
*She was not aware the override capability had been used by the staff for other purposes than

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A 489	Continued From page 18 emergent situations and should have been. *The investigation consisted mostly of chart review versus process review for a potential need in change with them. *Staff documentation had been the biggest concern with that case. *There was no documentation from the DDIRT to support: -They had reviewed internal security and accountability for both controlled and non-controlled wasting processes. -A full investigation had been completed to determine a root cause analysis for the diversion. -What was implemented, reinforced, or changed with current policies and processes to ensure a drug diversion of that magnitude would not occur again. *The provider had relied upon the mandatory training on drug diversion to educate the staff vs taking an active role for that concern. *She stated: -"With The Joint Commission we have 45 days to complete a root cause analysis on our occurrences." -"We only looked at the Propofol for diversion because there was so much taken." -"We did get together and did a debrief on this to see what we could have done better. No, I don't have documentation to support that." -"When I was completing the 106 Form [Drug Enforcement Administration form] was when I recognized we probably should be doing more." *She agreed the incident report that had been submitted to the SD DOH was 14 days late. *Surveyor requested the provider's policy on the process for med destruction and accountability for non-controlled meds. Review of the 5/31/23 Drug Enforcement	A 489		

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Administration (DEA) form 106 revealed:
*It supported:
-There had been an employee theft and when it was first discovered on 5/31/23.
-There was no documentation to support why the law enforcement had not been notified.
*The corrective measures the provider had implemented to prevent future theft or loss had been:
-"Increased employee monitoring."
-"Provided security training to the staff."
-"Pandemic and Health emergency relaxations surrounding documentation have recently been reversed (tightened) on the unit in question. Additional training for staff and higher expectations of documentation are added to procedural guidelines."
*The form requested to enter additional remarks if required. The following documentation from the provider was added:
-"Description of how theft or loss occurred."
-"Several bags of propofol and fentanyl had lacked documentation."
-There was no description on how their investigation identified that documentation in the eMar (electronic medical record) was a contributing factor for the drug diversion.

Through interviews, process reviews, and document reviews, there was no evidence that all those corrective measures documented on the DEA form 106 had:
-Identified areas of concern.
-Been implemented.
-Been changed on any policies, processes, or guidelines provided to the surveyor for review.
-Required staff education on those new and implemented process changes.

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A 489	Continued From page 20 Interview on 7/6/23 at 3:10 p.m. with chief compliance officer C revealed: *The DDIRT was a committee developed to specifically review drug diversions and they only met when a suspected diversion occurred. *She agreed: -A full investigation had not been completed to determine the root cause of the drug diversion -There were no processes reviewed for possible change to ensure the removal of the drug diversion risk had occurred. -Emails and only chart reviews would not have been considered a complete and full investigation. -There should have been documentation to support what actions or process changes they had considered changing and why. -After the review, the provider was still at risk for a drug diversion to occur. *Surveyor again requested the provider's policy on the process for med destruction and accountability for non-controlled substances. Interview on 7/6/23 at 4:45 p.m. with Accreditation Manager D revealed: *Propofol should have been considered a high-risk med because it was known to have been highly diverted. -There should have been process changes reviewed and implemented for the accountability and security of that med. *She confirmed: -The staff who worked in the ED and PICU had viewed the Propofol and the security of that drug as nothing to worry about because it was not a controlled substance. -With the current waste process for the Propofol in the large waste containers created the potential for drug diversion.	A 489		

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A 489	Continued From page 21 *Surveyor again requested the provider's policy on the process for med destruction and accountability for non-controlled substances. Review of the 12/15/20 director of hospital pharmacy job description revealed: *"Directs the procurement, storage and distribution of pharmaceuticals and the dissemination of pharmaceutical product information....." *"Responsibilities include.....evaluating department performance and implementing appropriate improvement plans; ..... and addressing complaints and resolving problems." *"Maintains and recommends enhancements to department policies and procedures governing all pharmacy operations and monitors implementation and compliance with hospital-wide policies." Review of the 3/12/19 pharmacy manager job description revealed: *Oversees the clinical and distributive pharmacy services for the pharmacy in accordance with professional standards, regulatory and licensing agency policies, and federal and state laws related to the practice of pharmacy." *"The manager must utilize effective problem solving skills as appropriate and accept personal responsibility and accountability for the patient's and department's outcomes." *"Responsibilities include....evaluating department performance and implementing appropriate improvement plans;.....and addressing complaints and resolving problems." Review of the provider's August 2021 Medication Administration policy revealed: *"Medication administration is documented after	A 489		

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AVERA MCKENNAN HOSPITAL & UNIVERSITY HEALTH CENTER	1325 S CLIFF AVE POST OFFICE BOX 5045 SIOUX FALLS, SD 57117

(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
A 489	Continued From page 22 the medication is administered." *"High alert medications are medications involved in a high percentage of errors and/or sentinel events as well as medications that carry a higher risk for abuse or other adverse outcomes." *There was no documentation to support the process for wasting both controlled and non-controlled medications in vials, IV bags, IV tubing, and syringes. Review of the provider's June 2021 Monitoring Controlled Substance Utilization and Documentation policy revealed: *"To ensure the safe and appropriate utilization of controlled substances while describing the standardized review process for proactive and retroactive review that may identify potential drug diversion or unaccounted for controlled substances within the organization." *"Each Avera facility should have a Drug Diversion Investigation Response Team (DDIRT) in place to evaluate any suspected drug diversion." -There was no documentation to support a process was in place for the DDIRT to follow when investigating a suspected drug diversion. *Escalation: -"Department of Criminal Investigation or local law enforcement will be contacted ....." -"The following reports shall be filed by the pharmacist-in-charge or other designated pharmacy leader within 24 hours, or as soon as possible in accordance with federal and state laws and guidelines. --a. Reporting to Licensing Board. --b. Reporting to Board of Health [SD DOH]. --c. Notification to the DEA." Review of the provider's December 2023 Pyxis	A 489		

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A 489	Continued From page 23 ES [Enterprise Server] policy revealed: *"Medication orders not on profile may be removed by override by the nurse during certain circumstances. The use of the override function will be guided by the condition of the patient. Appropriate use of the override function is defined as: -The physician is present at the time the drug is administered OR -The condition of the patient is such that the patient would be harmed by waiting for review of the medication (urgent situation)." *"The pharmacy is responsible for review of medications removed by override. Variances in the use of override will be documented and reviewed with nursing leadership." -There was no documentation to support how often the pharmacy completed these reviews. A policy and procedure for the medication waste and destruction process for non-controlled substances was not provider to the survey team by the time of exit from the facility on 7/13/23 at 4:00 p.m.	A 489		8.22.23

South Dakota Department of Health

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S 000	Compliance/Noncompliance Statement A complaint health licensure survey for compliance with Administrative Rules of South Dakota, Article 44:75, Hospital, Specialized Hospital, and Critical Access Hospital Facilities, was conducted from 7/5/23 through 7/6/23 and on 7/13/23. Areas surveyed included patient rights, pharmaceutical services, and nursing services. Avera McKennan Hospital & University Health Center was found not in compliance with the following requirement: S253.	S 000		
S 115	44:75:01:07 Reports Each facility shall fax, email, or mail to the department the pertinent data necessary to comply with the requirements of all applicable administrative rules and statutes. Any incident or event where there is reasonable cause to suspect abuse or neglect of any patient by any person shall be reported within 24 hours of becoming informed of the alleged incident or event. The facility shall report each incident or event orally or in writing to the state's attorney of the county in which the facility is located, to the Department of Social Services, or to a law enforcement officer. The facility shall report each incident or event to the department within 24 hours, and conduct a subsequent internal investigation and provide a written report of the results to the department within five working days after the event. Each facility shall report to the department within 48 hours of the event any death resulting from other than natural causes originating on facility property such as accidents or suicide patient. The facility shall conduct a subsequent internal investigation and provide a written report of the	S 115		

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

TITLE: President & CEO

(X6) DATE: 8/29/23

STATE FORM 6899 XEED11 If continuation sheet 1 of 11

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S 115	Continued From page 1 results to the department within five working days after the event. Each facility shall report a missing patient to the department within 48 hours. The facility shall conduct a subsequent internal investigation and provide a written report of the results to the department within five working days after the event. Each facility shall also report to the department as soon as possible any fire with damage or where injury or death occurs; any partial or complete evacuation of the facility resulting from natural disaster; or any loss of utilities, such as electricity, natural gas, telephone, emergency generator, fire alarm, sprinklers, and other critical equipment necessary for operation of the facility for more than 24 hours. Each facility shall notify the department of any anticipated closure or discontinuation of service at least 30 days in advance of the effective date. Each facility shall report to the department any unsafe water samples for pools or spas. This Administrative Rule of South Dakota is not met as evidenced by: Based on review of the South Dakota Department of Health (SD DOH) complaint intake information and interview, the provider failed to ensure a report was submitted to the SD DOH following the misappropriation of use for both controlled and non-controlled medications by one of one registered nurse (RN) (A). Findings include: 1. Review of the provider's 6/14/23 final incident report investigation submitted to the SD DOH on suspicion of misappropriation of meds by RN A	S 115		

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S 115	Continued From page 2 for both controlled and non-controlled meds revealed: *The report was submitted to the SD DOH 14 days after the identification and suspicion of the drug diversion had occurred on 5/31/23. -An initial report should have been submitted to the SD DOH within 24 hours of the identification of the suspicion of drug diversion. *He had been employed with the facility since 9/6/20. *A co-worker had brought forward a report suspecting him of diverting (stealing) drugs. *An investigation was opened on RN A for a possible drug diversion. *RN A: -Required disciplinary action and he was terminated on 5/31/23 for reasonable suspicion of drug diversion that occurred from 2/4/23 through 4/24/23. -Admitted to poor and sloppy documentation, but had not admitted to diverting any drugs. *Through the provider's investigation the following list of meds had been unaccounted for: -Fentanyl (pain medication) 4 bags. There was no documentation to support the dosage of the med nor the milliliters (ml) in the bags. -Propofol (anesthetic used for sedation) 12 bottles [vials]. There was no documentation to support the size and amount of medication that was in those vials. *"Through the investigation, we do not believe any patients were harmed as a result of this employees activities." -There was no documentation to support how the investigation had been completed to support no harm to the patients had occurred. *The abuse/neglect allegation for RN A was not substantiated since he had not admitted to the diversion of those meds. *The action taken by the provider to ensure a	S 115	Suspected/potential diversion or significant loss of controlled substance process: Can be reported through variety of methods 1. Individual suspicion of colleague/co-worker 2. Self-reporting 3. Anonymous report 4. Changes in work quality or frequency noted by others 5. Data anomalies detected by regular data review or noted through other mechanisms 6. Other Once reported to any member of the Quality/Risk or Pharmacy teams, the Chair/Moderator of the DDIRT team is notified Chair/Moderator confers with appropriate leadership (nursing, pharmacy, risk management, HR, or others as dictated by situation) and schedules initial meeting of the committee as indicated. Invitees include the available members of the core DDIRT team as identified in policy plus additional personnel/leaders as necessary to initiate an investigation. At first meeting, the DDIRT team reviews initial information and determines specific review and investigation to occur. Minutes are kept at all meetings and are maintained separately from case file specific information. Subsequent investigative work and meetings are scheduled as needed. Reorganization and Revamp of the Drug Diversion Team - DDIRT team will be chaired by a neutral party with experience in Pharmacy and compliance matters. - This person will initiate the DDIRT meeting after becoming aware of an issue/suspicion. - Once DDIRT team is initiated, Risk will place a DOH report under suspicion DDIRT meeting - There will be an agenda for each meeting - There will be minutes kept for each meeting o This will include the case number - The case information will be stored outside of the minutes in a Case Folder o To include all documents of the investigation - If team concludes a full investigation is needed o DDIRT team to do internal investigation to conclude there is legitimate suspicion or cannot be ruled out - Appropriate entities notified *Pharmacy contact DEA *Pharmacy contacts Board of Pharmacy - 106 form *Risk Management contacts DCI *Risk Mangement reports to licensing firm - Investigation complete - Risk to finalize formal DOH report from suspicion to submitted Proactive monitoring - Pharmacy Technology Team - Review for any significant discrepancies or data anomalies Daily, M-F - Discrepancy and documentation review with inpatient nursing leaders - daily - Control Check, currently, with a diversion monitoring/detection tool Daily M-F - Improvements/upgrades due in early 2024 - If Discrepancy is unable to be resolved or suspicion of diversion is identified, reported to Control Substance Coordinator, Chair of DDIRT team, Risk Manager, Pharmacy Leader, or Compliance Hotline - Discrepancies and audits reported to the Quality Committee quarterly as consent agenda items and Regional Controlled Substance Committee quarterly on going Regional Controlled Substance Committee - Meet Quarterly - DDIRT agenda and minutes to become a consent agenda item - DDIRT action/correction items to be discussed at meeting - Audit reports, discrepancies, as well as diversion investigations	8.22.23

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S 115	Continued From page 3 drug diversion of that magnitude would not occur again was to terminate RN A. *There was no documentation to support the following: -Facility procedures and processes for drug security had been reviewed or revised to ensure the diversion of meds would not occur again. -Personnel education or re-education on the current or revised policies for med security had been completed. Interview on 7/6/23 at 9:25 a.m. with controlled substance coordinator J revealed: *She confirmed There had been a recent drug diversion investigation on the intensive care unit. *Staff documentation had been the biggest concern with that case. *She stated: "With The Joint Commission we have 45 days to complete a root cause analysis on our occurrences but for the DOH it is much sooner." *She agreed: -The incident report that had been submitted to the SD DOH was 14 days late. -The provider should have submitted an initial report to the SD DOH within 24 hours of the initial notification regarding a potential drug diversion.	S 115	Education for this process as follows: Completed in person to leaders. Education provided to staff online after leaders education. New staff receive education in orientation as well as a module online to complete. Leaders of each area confirm that employees have completed education after their orientation is done. The education is included in staff orientation education.	8 22.23
S 253	44:75:06:04 Patient Care Plans and Programs The facility shall provide nursing services that provide safe and effective care from the day of admission through the ongoing development and implementation of written care plans for each patient. The care plan shall address medical, physical, mental, and emotional needs of the patient. The facility shall establish and implement procedures for assessment and management of symptoms including pain.	S 253		

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S 253	Continued From page 4 This Administrative Rule of South Dakota is not met as evidenced by: Based on record review, interview, and policy review, the provider failed to ensure: *Skin assessments at the time of discharge were documented for two of two closed sampled patient records (2 and 3) who had alteration in skin integrity on their heels. *A referral had been made for wound consultation for one of two closed sampled patient records (2) with altered skin integrity on her bilateral heels. Findings include: 1. Review of patient 3's medical record revealed: *She was admitted on 12/30/22 and discharged on 1/10/23. *Her admitting diagnoses were diabetes mellitus, acute pyelonephritis, severe dehydration, acute kidney injury, sepsis, and a urinary tract infection. Review of the nursing care assessment notes of patient 3's left heel ulcer revealed: *On 12/29/22 at 3:21 p.m. and at 9:30 p.m., the area was described as: -Wound bed appearance was open, red, blanchable, and moist. -There was a scant amount of bright red drainage with no odor. -The dressing included an abdominal dressing pad, Kerlix, and was changed at the above times. Review of the nursing care assessment notes regarding patient 3's left heel ulcer revealed: *On 12/30/23 at 8:35 a.m.: -Wound bed area was not observable due to dressing. -Surrounding tissue status was pink, cool, and scaly. -Wound drainage amount was none.	S 253	1. Unit Leader or designee will review pts with pressure ulcers on Day shift and Night shift, for 90 days, ending 11.15.23. At that time we will reassess. - Education was provided to Resource nurses by nursing leaders in an email, daily line up and face to face prior to their first shift - The Unit leader or designee will use the Wound Dashboard to identify all patients with pressure ulcers on the unit - The dashboard link will be emailed to Unit leadership and placed as a shortcut on their desktop - Audits will include 1. Admission/Transfer skin check completed Yes/No 2. Skin Documentation completed BID Yes/No 3. Is there a Wound Consult Order Yes/No 4. If WOC Consult, WOC order Yes/No 5. If WOC order, are orders done Yes/No 6. Is patient being discharged today Yes/No 7. If Yes, does discharge packet include skin information and treatment Yes/No 2. Just in time education to be done by Unit Leader or designee if items are not complete - Education to include the Skin policy/Algorithm 3. Audit Complete Spreadsheet to be completed by Unit Leader for tracking of daily/nightly completion 4. Second layer of review to be done by Unit AVP to verify completion 5. If items are not completed, correction plan in place by CNO 6. Monthly reported out to the Skin Wound Assessment Team by each each unit leader every month. This process will continue for the next 90 days 7. Quarterly - Action plan and Data summary to be reported to the Avera McKennan Quality Committee for approval and further direction 8. New Nurse orientation education will be completed by the Quality, Risk, and Service Director, along with a module in the new hire education 9. Education is then tracked by the leader of the unit with required completion after their first 30 days of employment	8.22.23

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S 253	Continued From page 5 -Wound dressing/closure was foam. -Wound dressing/closure/packing documentation was "changed by Wound RN [registered nurse] 12/30 --mepilex placed by wound RN." Review of patient 3's nursing care assessment notes regarding the left heel ulcer revealed: *On 12/30/22 at 8:00 p.m.; 12/31/22 at 8:36 a.m., 12/31/22 at 8:00 p.m.; 1/1/23 at 8:00 a.m. and 8:00 p.m.; 1/2/23 at 8:05 a.m. and 1/2/23 at 8:00 p.m.; 1/3/23 at 10:19 a.m. and 1/3/23 at 8:55 p.m. the wound was not observable, a Mepilex dressing was on, dry, and intact. *On 1/4/23 at 8:00 a.m. and on 1/4/23 at 8:00 p.m.: -The wound bed was open, pink, and red. -There was no drainage and the Mepilex was changed. *On 1/5/23 at 9:14 a.m.; 1/6/23 at 8:00 a.m., and 1/6/23 at 9:25 p.m.: -The wound bed appearance was open, pink, and red. -Surrounding tissue was normal for race, intact, and pink. -There was no odor and the Mepilex dressing was changed. Interview and review of patient 3's medical record on 7/6/23 at 8:15 a.m. and again at 10:00 a.m. with quality director P confirmed: *On 1/6/23 at 9:25 p.m. was the last documented assessment in patient 3's medical record. *On 1/7/23 no documentation was found on the heel ulcer. -On 1/8/23 at 8:21 p.m. the heel ulcer was not observable due to dressing, surrounding tissue was normal for race, intact, and pink. --A Mepilex dressing was in place. -On 1/9/23 at 7:55 a.m. and 7:57 p.m. the heel ulcer was not observable due to dressing,	S 253		

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S 253	Continued From page 6 surrounding tissue status was normal for race, intact, and pink, --Mepilex dressing dry and intact. *On 1/10/23 (day of discharge) at 8:33 a.m. the heel ulcer was not observable due to dressing, surrounding tissue status was normal for race, intact, and pink. -No further nursing documentation for the left heel ulcer was noted on the care assessment form. *The wound care nurse on 12/30/22 and on 1/5/23 had assessed her left heel and described it as a skin tear that: -Was open, red, and moist. -Measured 1.0 centimeters (cm) in length, width 1.5 cm, depth 1.50 cm, and with scant drainage. -Optifoam was applied and should have been changed every three days. *She was not sure why nursing and the physician had described the area as a heel ulcer. *The 1/10/23 discharge instructions had not mentioned a heel ulcer or care instructions for the heel ulcer. Interview and record review on 7/6/23 at 3:46 p.m. with director of medical support K confirmed: *The dressing should have been changed on 1/8/23. *There was no documented dressing change for that day. *The area had been documented as not observed due to dressing. *There was no documented assessment of the wound prior to discharge. Interview and review of patient 3's medical record on 7/6/23 at 9:15 a.m. with wound care nurse Z regarding patient 3's wound care assessments revealed: *She had identified the left heel wound as a skin	S 253		

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S 253	Continued From page 7 tear, she was not sure why staff had documented a left heel ulcer. *Her assessment on 12/30/22 revealed: -A skin tear on the left heel that was present on admission. -The wound appearance was pink, red, and moist. -The surrounding tissue was intact and pink. -The area was open to air. *Her assessment on 1/5/23 revealed: -A skin tear on the left heel that was present on admission. -Wound appearance open, red, and moist. -Wound length 0.5 cm, width 1.0 cm, area 1.50 cm. -Surrounding tissue appearance was intact and pink. -Wound drainage was scant without odor. -Saline was used to cleanse the wound. -The wound dressing was changed. -The wound measured smaller and continued plan of care. *The wound care nurses completed wound measurements for consistency and accuracy. *The patient was seen weekly. *The dressing was changed every three days. 2. Review of patient 2's medical record revealed she: *Was admitted on 12/21/22 for an unresponsive episode. *She was discharged on 12/28/22. *Diagnoses included but not limited to diabetes mellitus, atrial fibrillation, and a stage II sacral ulcer. Review of the 12/21/22 initial nursing wound/incision assessment documentation revealed:	S 253		

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S 253	Continued From page 8 *She had bilateral heel inflammation that was present on admission. *The heels were described as: -Wound bed appearance was dark red, non-blanchable, and boggy. -The surrounding tissue status was pink and boggy. -No drainage or odor. -Areas were open to air. Review of the wound care nurse progress notes dated 12/22/22 and 12/28/22 revealed there was no assessment documented for patient 2's heels. Review of the nursing documentation for 12/28/22 revealed there was no assessment or description of the patient's heels at the time of discharge. Review of the physician's 12/21/22 History and Physical report and the 12/28/22 Discharge Summary report revealed neither documents: *Assessed or described the condition of patient 2's heels. *Listed the heels as a problem area. Interview and review on 7/6/23 at 4:46 p.m. of patient 2's physician orders from 12/21/22 to 12/28/22 with director of medical support K confirmed: *There was no physician order for the wound care nurse to conduct an assessment. *Nursing staff should have followed the wound algorithm to assist with making a referral to the wound care nurse. *The algorithm indicated upon admission if the skin assessment revealed open areas, reddened and/or non-blanching areas then a wound care consult should have occurred. Interview and review on 7/13/23 at 1:35 p.m. of	S 253		

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S 253	Continued From page 9 patient 2's medical record with director of wound care AA and wound care nurse BB revealed: *Bedside nurses were responsible for documenting the patient's skin condition. *The condition of the heels during her stay was described as red, boggy, and non-blanchable. *They were not involved with the care, had not been consulted, and their involvement was at the nurse's discretion for that patient, as the heels had no open area. *The skin assessment policy and algorithm were for reddened and non-blanchable areas over bony prominences and would not apply here. -That was not clearly identified in either document. 3. Interview on 7/13/23 at 12:45 p.m. with registered nurse CC regarding nursing skin assessments revealed: *Upon admission two nurses performed a head-to-toe nursing assessment. *Skin concerns were documented on the wound/incision form. *There was no process for a head-to-toe assessment of the skin at the time of discharge. *It was the nurse's responsibility to document skin condition at the time of discharge. *Majority of the patients went to another unit as they improved. At that time, two nurses on the receiving unit went through the same head-to-toe nursing assessment and documented the patient's skin condition. Interview on 7/13/23 at 1:00 p.m. with supervisor DD revealed: *Staff conducted wound assessments every four hours. *It was not included in the discharge process to assess wounds. *For non-blanching skin areas a wound consult	S 253		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	10563 S	A. BUILDING: _____ B. WING _____	C 07/13/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
AVERA MCKENNAN HOSPITAL & UNIVERSITY HEALT	1325 S CLIFF AVENUE POST OFFICE BOX 5045 SIOUX FALLS, SD 57117

(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) COMPLETE DATE
S 253	Continued From page 10 would have been ordered. 4. Review of the August 2021 Skin Assessment and Care --Inpatient Acute Hospital, AMcK (Avera McKennan) specific info policy revealed: *The wound care nurse and/or the provider should have been notified if any of the following skin conditions were identified: -Open skin areas. -Reddened and non-blanchable areas. -Any skin impairment under a medical device. -Any worsening of previously identified skin issues. *The policy addressed care of skin tears, contained an air mattress algorithm, and a wound consult algorithm. *It described deep tissue injury as non-blanching areas on the specialty bed air mattress ordering algorithm. Review of the May 2023 Skin Assessment and Care policy revealed: *"Purpose: To provide guidelines and direction for healthcare professionals in assessing and providing care and intervention to patients with skin issues and to prevent the development of skin issues." *"4. Documentation" included skin risk assessment intervention, skin issues in the wound/incision intervention, and communication regarding skin integrity issues with the provider or wound care nurse."	S 253		

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	430016	A. BUILDING _____ B. WING _____	C 09/07/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
AVERA MCKENNAN HOSPITAL & UNIVERSITY HEALTH CENTER	1325 S CLIFF AVE SIOUX FALLS, SD 57117

(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
A 000	INITIAL COMMENTS A re-visit survey (SD00002014 and SD00002016) was conducted on 09/05/23, the facility was found in compliance with 42 CFR 482.25 - Pharmaceutical Services; subsequently a complaint survey (SD00002048) was conducted on 09/07/23 and it was determined that the facility demonstrated continued non-compliance with the condition 42 CFR 482.13 - Patient Rights.	A 000		
A 115	PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on a review of the South Dakota Department of Health (SDDOH) complaint intake information, plan of correction (POC) review from the 7/13/23 complaint survey, interview, record review, and policy review, the provider failed to complete a full investigation on a grievance submitted by one of one sampled patient (1) who felt "violated" while receiving assistance from one of one personal care technician (PCT) (A). Findings include: This failure has the potential to cause harm to other patients since a full investigation to ensure all patients were safe and free from harm was not conducted. 1. Review of the provider's 9/5/23 final incident report investigation submitted to the SDDOH revealed: *The date of the event occurred on 9/4/23 at 10:30 p.m. between patient 1 and PCT A. *On 9/5/23 at 7:00 a.m. registered nurse (RN) B	A 115	Tag A 115 The Chief Nursing Officer is responsible for implementing the plan of correction and for overall and on-going compliance. The Chief Nursing Officer (CNO) held a meeting on September 11, 2023 including nurse managers, Senior Director - Medical Support Services, Quality Director, Quality Initiatives Director and Risk Manager to review the findings and provide direction for an effective plan of correction as follows: On September 13, 2023, a "Reporting Suspected Abuse Checklist" was drafted to provide guidance and direction for Nurse Leaders and Resource Registered Nurses (RRN). This checklist will be initiated immediately following any reported abuse. Content is as follows: 1) Complete before end of shift - date and time of incident, when staff made aware, when RRN notified, confirm	10/2/2023

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

President + CEO 09/29/2023

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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SEP 29 2023
SD DOH-OLC