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	431323	A. BUILDING _____ B. WING _____	09/19/2024

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MONUMENT HEALTH CUSTER HOSPITAL	1220 MONTGOMERY STREET CUSTER, SD 57730

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C 000	INITIAL COMMENTS A recertification health survey for compliance with 42 CFR Part 485, Subpart F, Subsections 485.605-485.645, requirements for Critical Access Hospitals (CAH) and Long Term Care Services ("swing bed"), was conducted from 9/17/24 through 9/19/24. Monument Health Custer Hospital was found not in compliance with the following requirements: C0890, C1004, C1300, and C1616.	C 000		
C 890	BLOOD AND BLOOD PRODUCTS CFR(s): 485.618(c)(1) The facility provides, either directly or under arrangements, the following-- (1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the provider failed to ensure the blood bank alarm system sounded at the appropriate temperature to ensure a prompt response when the internal blood storage refrigerator temperature was not maintained within the correct range for three of three quarterly alarm tests (2/21/24, 5/13/24, and 7/1/24) reviewed. Findings include: 1. Observation on 9/17/24 at 9:50 a.m. of the laboratory's blood bank refrigerator revealed the refrigerator contained two units of O positive and two units of O negative packed red blood cells available for transfusion to patients. Review on 9/17/24 at 9:55 a.m. of the laboratory's	C 890	BLOOD AND BLOOD PRODUCTS The Manager of Laboratory is responsible for the compliance of this tag; and has educated all Laboratory Technicians to policy: *Testing Blood Bank Alarms: Refrigerator, Freezer and Platelet Incubator* by 10/07/2024 and any employees on leave will be educated by Manager of Laboratory prior to their first shift returning to work. Newly hired Laboratory Technicians or Technologists will receive this training during onboarding. Monitoring: Alarm testing will be conducted monthly by Laboratory Technicians with documentation of high and low temperatures with documentation of prompt actions taken if temperatures not in range of acceptable blood bank temperatures between 1 Celsius and 6 Celsius. The results of this monthly log will be done until 4 consecutive months of greater than 90% compliance is achieved and will be reported monthly to QAPI, the pathologist and the Advisory Board by the Manager of the Laboratory.	10/07/2024

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

Barb Hespen ONP, RN | Market President | 10/11/2024

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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C 890	Continued From page 1 blood bank Quarterly Alarm Check form revealed: a. On 2/21/24: *Blood bank refrigerator high alarm activation temperature was 6.6 C (Celsius). *Blood bank refrigerator low alarm activation temperature was 0.29 C. *Acceptable blood bank refrigerator alarm activation temperatures had been <6 C and >1 C. b: On 5/14/24 *Blood bank refrigerator high alarm activation temperature was 40.6 C. *Blood bank refrigerator low alarm activation temperature was 0.68 C. c. On 7/1/24 *Blood bank refrigerator high alarm activation temperature was 42.8 C. *Blood bank refrigerator low alarm activation temperature was 0.4 C. d. Each of the above quarterly blood bank alarm checks had been performed by different laboratory personnel. e. There had been no documentation the alarm had sounded in the laboratory. f. There had been no documentation of the temperature comparison with the blood bank refrigerator's continuous temperature monitoring graph and the documented alarm activation temperature. g. There had been no documentation of corrective actions taken for any of the above quarterly alarm checks. h. The above quarterly alarm checks had been reviewed and found acceptable by laboratory manager F and laboratory consultant K. Interview on 9/17/24 at 10:00 a.m. with laboratory lead technician I revealed: *She confirmed the laboratory had maintained a minimum inventory of two units of O positive and	C 890		

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C 890	Continued From page 2 two O negative packed red blood cells for emergency release to transfuse to patients. The laboratory had also received additional crossmatched units of packed red blood cells from a [out of town] hospital for transfusion to patients. These units had been stored in the blood bank refrigerator prior to transfusion. *She confirmed that the blood bank refrigerator temperature had been continuously monitored via a temperature monitoring strip that had been changed monthly. *She confirmed the blood bank refrigerator had also been continuously monitored remotely in [out of town]. *If the blood bank refrigerator temperature exceeded the safe storage temperature, the alarm would sound at the remote monitoring station. Personnel at the remote monitoring station would contact the laboratory informing them the blood bank refrigerator alarm had activated and the current refrigerator temperature. *She did not know how quickly the remote monitoring station had called the laboratory after the blood bank alarm had been activated. *She confirmed acceptable blood bank alarm activation temperatures had been above 1 C and below 6 C. *She had followed the laboratory's blood bank alarm activation procedure when completing the quarterly alarm activation checks. *She had used chilled water and slowly warmed the water to verify the alarm activation temperatures. *She confirmed the temperatures documented on the log had been the temperatures reported by phone by the remote monitoring station located in [out of town].	C 890		

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C 890	Continued From page 3 Interview on 9/18/24 at 11:00 a.m. with laboratory medical technician J revealed: *She confirmed she had completed the quarterly blood bank alarm check in the past. *She had followed the laboratory's blood bank alarm activation procedure when completing the alarm activation checks. *She had used tap water, "but not really hot water", for the high temperature alarm check. She would then add ice to lower the temperature of the water for the low alarm activation temperature. *She documented the temperature reported by telephone from the remote monitoring station. *She had not used a thermometer along with the temperature probe during the activation temperature. *She agreed, she should have used a thermometer during the quarterly activation temperature check to verify the activation temperature. Interview on 9/19/24 at 11:40 a.m. with laboratory manager F revealed: *She confirmed she had reviewed the quarterly alarm checks. *She agreed the results had not been acceptable. *She stated she only checked to ensure the quarterly alarm had been completed. She had not verified whether the temperatures had been acceptable. *She stated they only checked one of the two temperature probes. They did not verify if the alarm would sound in the laboratory or would be documented on the monthly continuous temperature monitoring strip. Interview on 9/19/24 at 11:50 a.m. with laboratory consultant K revealed:	C 890		

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C 890	Continued From page 4 *She had made monthly visits, when possible, to the laboratory to review laboratory records. *She confirmed she had reviewed the quarterly blood bank alarm activation checks. *She did not know what the acceptable results for the blood bank refrigerator alarm activation temperatures should have been. Review of the laboratory's Testing Blood Bank Alarms: Refrigerator, Freezer, and Platelet Incubator procedure, last revised on 7/2024, revealed: *"Principle: ... The high and low temperatures of activation must be checked, and the results recorded. Alarms, according to the AABB [Association for the Advancement of Blood and Biotherapies] Standards, must be set to activate at a temperature that will allow proper action to be taken before the blood or components reach an undesirable temperature." *"The audible alarms include: A. Alarms on the equipment to notify personnel at the location, and B. Remote alarms to notify staff at alternate locations (Nurses Station or Command Center depending on facility operations) in the event that the laboratory is not staffed. C. Quarterly checks are performed on all on site and remote audible alarms." *"Procedure Guidelines (for [names of facilities included in the procedure]) Always check the low activation first. 1. Low Alarm Activation: a. Fill an 8 ounce glass half full of chilled water (4 C). b. Use crushed ice or break ice cubes into smaller pieces and place in a separate container. c. Remove the thermometer sensor from the solution bottle, tape this sensor to the test	C 890		

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thermometer (or use rubber bands) and insert into the glass.
d. Also place thermometer sensor from "empty" bottle and place in glass.
e. Stir the test thermometer/monitor sensor in a circular motion, slowly add ice at the proper rate to provide a temperature drop of 0.5 C/minute.
f. Log the low alarm activation.
g. Compare the temperature at which the alarm sounds to the temperature of the recording graph.
2. High Alarm Activation:
a. Slowly add warm water to the ice slurry at the proper rate to provide a temperature rise of 0.5 C/minute.
b. Constantly stir the test thermometer/monitor sensor as in Step "e' above.
c. Log high alarm activation.
d. Compare the temperature at which the alarm sounds to the temperature on the recording graph.
3. Check and log reaction of remote monitor during these test procedures if applicable.
4. A notation should be made on the temperature recording graph that explains any out-of-range temperature registered as a result of the alarm check.
5 The rate of the rise and fall of the liquid temperature used in testing is critical. Observe the 0.5 C/minute rate of change or testing errors will occur."
*"Limitations:
3. When the temperatures of activation are checked, the change in temperature should be allowed to occur at a rate that allows slowly responding thermocouples to be accurately measured. Too rapid a change in temperature may give a false impression that the alarm does not sound until a higher temperature is registered.
4. The low temperature for activation for

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C 890	Continued From page 6 refrigerators should be no lower than 1 C; the high temperature of activation should be no higher than 6 C. Low activation temperatures above 1 C and high activation below 6 C do not conflict with the AABB standards. 7. Alarms should sound simultaneously at the site of the refrigerator and at the location of the remote alarms, if remote alarms are employed."	C 890		
C1004	PROVISION OF SERVICES CFR(s): 485.635 §485.635 Condition of Participation: Provision of Services This CONDITION is not met as evidenced by: Based on observation, interview, job description review, South Dakota (SD) Board of Pharmacy review, and policy review, the provider failed to ensure: *The regional pharmacy department had followed and maintained its Plan of Correction (POC) following the South Dakota Department of Health (SD DOH) survey conducted on 9/15/22. *Documentation to support unauthorized staff had received proper training, continuing education, and professional oversight from a pharmacist for one of one nursing assistant (NA) (P) who had access to and restocked medications in: -One medication room. -Two Omnicell medication dispensing units located in the medication room and emergency department. -Three emergency crash carts. -One clinic. *The regional pharmacy department maintained oversight and was involved with the internal medication process for one clinic. *The regional pharmacy department was involved with the quality assurance performance	C1004	PROVISION OF SERVICES The Director of Pharmacy is responsible for oversight of medication security and oversight of authorized staff in the medication room. The non-certified pharmacy technician is no longer working in her role at the Custer Hospital. The Pharmacy Department is in the process of training certified pharmacy technician to work full time in Custer after training with expected date of February 2025. In the interim, the Director of Nursing and Director of Pharmacy have re-instituted plan for licensed registered nurses to refill Omnicell daily and refill drawers in emergency crash carts. The nursing staff were educated to the process on 10/03/2024 by Director of Nursing and the information that the non-certified pharmacy technician is no longer working in her role. The Director of Pharmacy is responsible for oversight of medication security and oversight of authorized staff in the medication room of the Custer Clinic. The non-certified pharmacy technician is no longer working in her role at the Custer Clinic. The lead RN in the clinic will order/refill medication inventory of the clinic medication room with oversight of pharmacist's weekly visits. The narcotic cabinet is locked with a locked cabinet stores the keys to the narcotic box, with access to only those authorized to have access has been done by the Director of the Clinic with Director of	10/07/2024

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C1004	Continued From page 7 improvement (QAPI) committee to ensure all matters pertaining to the use of medications and pharmacy operations were reviewed and evaluated per their POC following the SD DOH survey conducted on 9/15/22. Findings include: 1. Interview on 9/17/24 at 8:50 a.m. of administrator A during the entrance conference revealed: *She stated Pharmacist E was the designated pharmacist and she had oversight of the pharmacy technician. -Nurse aide (NA) P was the designated pharmacy technician-in-training who was retiring in October of 2024. *She stated there was going to be a new pharmacy technician who would be certified by the time NA P retired. 2. Observation and interview on 9/17/24 at 9:45 a.m. with infusion registered nurse (RN) Q and NA P of the emergency room (ER) Omnicell (automated medication dispensing machine) revealed: *NA P was responsible for stocking the Omnicells with medications, including narcotics and scheduled drug medications. *RN Q stated there was no second-person oversight, or verification by a licensed caregiver when NA P stocked medications into the Omnicell machines. -The licensed nurses stocked the Omnicell machines when NA P was not working. *Pharmacist E was physically on-site once a week. -They could contact Pharmacist E, or a pharmacist at the parent hospital, by phone when they had questions or needed guidance.	C1004	Continued From page 7 Pharmacy oversight. Clinic Nursing staff will be educated on policy: Drug Security and Storage Policy by 10/07/2024 by the Director of the Clinic. Any clinic nursing staff on leave will complete training prior to first shift. Monitoring: Ongoing monitoring will be done by weekly observation by the Director of Nursing to ensure that medication safety, storage and medication management is done per policy by licensed RN. Reporting will be done monthly until 4 consecutive months of greater than 90% compliance is achieved and will be reported monthly to QAPI and the Advisory Board by the Director of Nursing. Ongoing monitoring will be done by sign-in sheet located in medication room in Hospital for Pharmacist &/or Pharmacy Technician to sign when onsite weekly for review of medication safety, storage, and security. This will be tracked monthly until 4 consecutive months of greater than 90% compliance is achieved and will be reported to the QAPI and the Advisory Board monthly by the Director of Nursing. Ongoing monitoring will be done by weekly observation by Director of Clinic to ensure that medication safety, storage and medication management is done by nursing staff in the clinic. Reporting will be done monthly until 4 consecutive months of greater than 90% compliance is achieved and will be reported to the QAPI and the Advisory Board by the Director of the Clinic. Ongoing monitoring will be done by sign-in sheet located in medication room in Hospital	

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C1004	Continued From page 8 3. Interview on 9/18/24 at 11:10 a.m. with NA P regarding her role as the pharmacy technician revealed: *She had worked for the provider since March of 2022 in the pharmacy technician role. -She worked in this role on Mondays, Tuesdays, and Fridays. On Wednesdays and Thursdays she worked at the local nursing home. *She was not a certified pharmacy technician. -She denied enrolling in or receiving further pharmacy education following her registration and receiving a pharmacy technician-in-training certificate in 2022. -She stated pharmacy personnel had not provided further in-person training, oversight, or refresher courses, since the initial two-week orientation at the parent facility in the spring of 2022, which was prior to her registering to be a technician-in-training. -She had completed one skills competency audit with a pharmacist after 2022, but could not recall when that occurred. -She had to tell the pharmacist how to complete the audit. -She had not received a pharmacy technician-in-training job description. -The only job description that she had was for a NA. *She was responsible for: -Ordering medications and restocking the two Omnicell machines, including narcotics and scheduled drugs. -Monitoring and removing outdated medications from the active Omnicell medication drawers. -Reviewing and restocking the emergency crash cart supplies, with oversight from a licensed nurse. -Reviewing Omnicell audit reports that were	C1004	Continued From page 8 for Pharmacist &/or Pharmacy Technician to sign when onsite weekly for review of medication safety, storage, and security. This will be tracked monthly until 4 consecutive months of greater than 90% compliance is achieved and will be reported to the QAPI and the Advisory Board monthly by the Director of Nursing.	

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C1004	Continued From page 9	C1004		

received from the parent hospital's pharmacy.
*She stated she refilled scheduled medications in the Omnicell without a second person verification system, and the Omnicell's scheduled medications only required a second person verification if the pill count had not matched the Omnicell pill count.
-She stated, "I don't feel I should be doing the narcs (narcotic medications). I'm a CNA (certified nurse aide)."
*She stated she was "suspended" from the pharmacy technician role for about three months following the 9/15/2022 South Dakota Department of Health (SD DOH) survey.
-The licensed nurses had refilled the Omnicell's during that time.
*She resumed the pharmacy technician role once she had registered and obtained a pharmacy technician-in-training certificate in the fall of 2022.
-She stated that licensed nursing "time constraints" was the reason she was asked to resume her pharmacy technician role.
*She stated she had not stocked the narcotics box in the adjacent clinic. "But the keys are there so anyone can have access."
*She was stepping down from her pharmacy technician-in-training role once her registration expired on 10/31/24.

Interview on 9/19/24 at 10:20 a.m. with regional pharmacy director D and Pharmacist E regarding NA P and her role as a pharmacy technician-in-training revealed:
*Regional pharmacy director D was responsible for oversight of the provider's pharmacy operations.
*Pharmacist E provided on-site visits every Thursday.
*Pharmacy director D stated pharmacy staff

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came from the parent hospital to teach staff about the Omnicell machines and how they operated.
*Regarding the pharmacy technician-in-training program regional pharmacy director D stated:
-"Without that program it's impossible to meet demand requirements."
-"I can train for everything, nothing requires a didactic (teaching method that uses lectures and textbooks instead of demonstrations) online course, that I know of."
-"There is no requirements from the board [SD pharmacy board] for tech-in-training [pharmacy technicians-in-training]."
-"A pharmacy technician requires 500 hours (three months) of experience or no experience but a completed certification."
*Regarding the pharmacy's oversight of NA P, regional pharmacy director D stated he had technicians come every couple of months for oversight, but he had no documentation to support this oversight.
*He stated:
-"We have techs train techs all the time."
-"Didn't know I needed to document oversight (of NA P). Almost positive it is not documented. I will look and see if there is any documentation on file."
-"No way to support this except by what I say."
*NA P was monitored by reviewing the Omnicell's records.
*Regional pharmacy director D confirmed he was the pharmacy director during the 9/15/22 SD DOH survey.
-He stated the reasons he had not followed the 2022 Plan of Correction (POC) was because he was told "the nurses were too busy" to restock the Omnicell's and that "none of the (pharmacy technician) applicants worked out."
*Pharmacist E stated she had performed some

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C1004	Continued From page 11 oversight of NA P when she was working on-site on Thursdays. -After being informed NA P had not worked on Thursdays, she stated, "I don't look for her, as of late I haven't seen her." Interview on 9/19/24 at 11:05 a.m. with administrator A and director of nursing (DON) C regarding NA P and pharmacy's oversight of her pharmacy technician-in-training role revealed: *Administrator A: -Felt it was not the best practice to have NA P in that role. -Stated "I'm responsible." *DON C stated,: -"We had hoped the pharmacy was providing her oversight." -"They told us that this would work and we would be okay." -"As a professional, you know, we rely upon them for that accuracy." *They both stated that licensed nurses were not limited by time constraints since they monitored and refilled the Omnicell's when NA P was not working. 4. Review of the QAPI meeting minutes from 1/25/23 through 7/25/24 revealed no documentation to support the pharmacy department had attended the meetings and presented on any identified concerns, pharmacy and therapeutics meetings, antibiotic stewardship program, med errors, and near misses. Refer to C1300. 5. Review of the 6/2/24 South Dakota Board of Pharmacy 50 SDR 138; 20:51:29:16 and 20:51:29:00 revealed:	C1004		

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C1004	Continued From page 12 *"The pharmacist-in-charge of a pharmacy shall ensure that a technician receives adequate training in the tasks performed by pharmacy technicians working at that pharmacy. A pharmacy utilizing a pharmacy technician shall develop, implement, and periodically review written policies and procedures for training and utilizing pharmacy technicians appropriate to the practice of pharmacy at that pharmacy....Each pharmacy shall document and maintain each technician's training for the duration of employment..." *"Definitions. 4. 'Technician-in-training,' an individual who is registered with the board to receive on-the-job training in a licensed pharmacy in preparation for certification as a pharmacy technician. A technician-in-training must become a certified technician within two years of registration with the board." Review of the provider's 4/9/24 Non-certified Pharmacy Technician job description revealed it had not included what amount of pharmacist training and oversight would be provided. Review of the provider's December 2022 Pharmacy Staffing, Orientation and Competencies policy revealed: *"Policy Statement. To provide guidelines for pharmacy staffing levels to meet patient care needs, support orientation of new caregivers and support the continued competency of pharmacy caregivers." -"D. Competencies. 3. Documentation is maintained within the department and available upon request. 5. Annual training requirements will be completed. 7. Technicians will receive up to four competencies per calendar year and will be documented by a pharmacy operations	C1004		

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C1004	Continued From page 13	C1004		

coordinator."

Review of the provider's February 2024 Medication Ordering, Receiving and Delivery policy revealed:
*"B. Receiving. 7. Controlled substance orders will be independently verified by a second caregiver and documented on the receiving document."

6. Surveyors had verbally requested copies of the pharmacy technician visits, education, audits, and oversight documentation of NA P from regional pharmacy director D, pharmacist E, and DON C. A non-certified pharmacy technician competency audit dated 3/14/23 was provided by DON C. No other pharmacy related audits, education, or oversight was provided by the end of the survey.

7. Observation and interview on 9/17/24 at 2:40 p.m. with RN M in the clinic medication room revealed:
*The room required a badge to access it and there was a camera located in the upper right corner of the room for extra security for the meds.
*There was a metal box on the counter with a lock that required a specialized key to open it.
-Inside of the metal box was the narcotic or controlled substances that required double locking.
-The nursing staff counted the meds for accuracy every day that they were open.
*The key to open the box was attached to a ring full of keys and was located in the cupboard above the locked box.
-The cupboard was not locked and the nurse was able to retrieve the keys without difficulty.
*RN M stated that they were told during their last survey that the keys could no longer be placed on

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C1004	Continued From page 14 the counter next to the metal box but had to be placed in the cupboard above it. *She agreed that was not a secure process and anyone could access them with the key right there. *She stated: -"But the room requires badge access and we do have a camera too." -"And we count every day." *The nurse confirmed that NA P: -Had access to the room and re-stocked the meds in two of the cupboards. -Would have had access to the narcotics and controlled substances because of where the key was stored. *She was informed that (NA P) worked and stocked meds under the direction of their pharmacy. Observation and interview on 9/18/24 at 1:20 p.m. with clinic director G in the clinic medication room revealed: *He had been the director of the clinic for approximately six months. *He was not aware of the process of how the narcotics or controlled substances had been secured and accounted for. *When he observed where the narcotics and controlled substances were stored and where the keys had been kept to open the box he stated "That key is not secure and anyone can access them with that process. The box might as well be unlocked." *He was aware NA P had access to the room and restocked certain meds for them. *He was not aware NA P was a nursing assistant and not a pharmacy tech. *He stated: -"I was told this was the process for her	C1004		

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C1004	Continued From page 15	C1004		

restocking meds and never questioned it further."
-"If this is not right, absolutely, we need to fix it."
-"We don't have a policy on med security for the clinic. All of our policies are linked to the hospital."

Interview on 9/19/24 at 10:30 a.m. with regional pharmacy director D and pharmacist E regarding the clinic medication room and med storage revealed:
*They had not been aware of the processes the clinic had implemented for med security and accountability.
*They were aware the clinic was licensed underneath the hospital and required oversight by them.
*Regional pharmacy director D stated:
-"We don't have oversight of the med security process over there and I agree we probably should."
-"I just never thought of it."
-"We don't oversee any of our clinics really."
-"Note to self."

Review of the provider's November 2023 Drug Security and Storage policy revealed:
*"The Pharmacy Department is in charge of drug security and storage at [hospital name] and monitors in accordance with Federal, State, and Institutional guidelines to prevent theft and/or unauthorized personnel from access to drug storage areas.
*Only authorized personnel will have access to drug storage areas, machines, cabinets or carts. Authorized personnel includes staff members providing care and services to patients including, but not limited to, medical staff, anesthesia, surgical staff, nursing, pharmacy, respiratory therapy, paramedics and ancillary support personnel as necessary to perform their assigned

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C1004	Continued From page 16 duties. 3. Access must be allowed under laws and regulations." *"Areas that do not have an ADS [automatic dispensing unit] shall have a locked cabinet or drawer to secure meds. a. The keys shall be carried by authorized personnel."	C1004		
C1300	QAPI CFR(s): 485.641 Condition of Participation: Quality Assessment and Performance Improvement Program The CAH must develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven quality assessment and performance improvement (QAPI) program. The CAH must maintain and demonstrate evidence of the effectiveness of its QAPI program. (a) Definitions. For the purposes of this section- Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. Error means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems; and Medical error means an error that occurs in the delivery of healthcare services. This CONDITION is not met as evidenced by: Based on observation, interview, Quality Assessment and Performance Improvement (QAPI) record review, job description review, and policy review, the provider failed to ensure: *The pharmacy department attended QAPI	C1300	QAPI The Director of Pharmacy has responsibility for oversight of all aspects of Pharmacy services at Monument Health Custer Hospital. Non-certified pharmacy technician is no longer working in her role. Weekly visits will be conducted by Pharmacist and Pharmacy Technician in training to the Custer Hospital site to review processes and compliance with pharmacy services. Omnicell dispensing machines will be refilled by licensed registered nurses with oversight by pharmacists beginning 10/07/2024. Pharmacist will attend monthly QAPI meetings to report any adverse events, medication errors, and/or any process issues regarding medication management for the Monument Health Custer Hospital. The Custer on-site Pharmacists have received education from the Director of Pharmacy on 10/11/2024 regarding the mandated requirement to attend monthly QAPI meetings in Custer to report adverse events, medication errors, any medication safety or storage issues and provide guidance/direction to promote patient safety.	10/11/2024

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C1300	Continued From page 17 meetings and identified, tracked, and reported the results of pharmacy-related improvement projects. *The pharmacy department had followed and maintained its Plan of Correction (POC) following the South Dakota Department of Health (SD DOH) survey conducted on 9/15/22. *Unlicensed staff had received proper training, continuing education, and professional oversight from a pharmacist or a licensed pharmacy technician to monitor, handle, and restock medications in two Omnicell's (automated medication dispensing machines). Findings include: 1. Observation and interview on 9/17/24 at 9:45 a.m. with infusion registered nurse (RN) Q and nurse aide (NA) P of the emergency room's (ER) Omnicell machine revealed: *NA P had registered as a pharmacy technician-in-training. *NA P stocked the Omnicell machines with medications, including narcotics and scheduled drug medications, when she worked on Mondays, Tuesdays, and Fridays. -There was no second-person oversight, or verification by a licensed caregiver when NA P stocked medications into the Omnicell machines. -The licensed nurses stocked the Omnicell machines when NA P was not working. *Pharmacist E was physically on-site once a week. -They could contact pharmacist E, or a pharmacist at the parent hospital, by phone if they had questions or needed guidance. Refer to C1004. 2. Interview on 9/18/24 at 9:25 a.m. with QAPI	C1300	Monitoring: The Clinical Quality Coordinator will monitor compliance with Pharmacist attendance at monthly QAPI meetings and will notify Market President if not meeting this measure. Reporting will be done monthly until 4 consecutive months of greater than 90% compliance is achieved, and this data will be reported to the QAPI and the Advisory Board by the Director of Nursing.	

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C1300	Continued From page 18 clinical coordinator N revealed: *QAPI meetings were held quarterly. *She stated neither pharmacist E nor regional pharmacy director D had provided pharmacy information or attended any QAPI meetings in 2024. -She had sent the pharmacists email invitations to attend either in person or by phone before each QAPI meeting, but they had not participated. -Pharmacist R, from the parent hospital, had last attended one QAPI meeting in September of 2023. *She stated she had notified administrator A and pharmacist R that pharmacists E and D had not been in attendance during QAPI meetings. 3. Review of the provider's 1/25/23 through 7/25/24 QAPI meeting minutes revealed no documentation to support the regional pharmacists had attended those meetings and reported to that committee on any monitoring or action plans that had been put in place for any concerns. 4. Interview on 9/19/24 at 10:20 a.m. with regional pharmacy director D and pharmacist E regarding QAPI attendance and reporting revealed: *They confirmed the pharmacy department had not been active members of QAPI meetings or participated in QAPI meetings per the Center for Medicare and Medicaid Services (CMS) regulations and provider policy. *Pharmacist E confirmed she is on-site once a week on Thursdays and stated she does not attend QAPI meetings or send any pharmacy reports to QAPI. *Regional pharmacy director D stated he had attended the medical executive committee meetings, but not the QAPI meetings.	C1300		

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C1300	Continued From page 19 -Regional pharmacy director D confirmed he was the regional pharmacist during the 9/15/22 SD DOH survey and was aware of the provider's POC indicating the director of pharmacy or a designated pharmacist should attend QAPI meetings. -He stated they had "sent pain reports to QAPI in the past, but QAPI had taken over that [monitoring]." -He agreed attendance and participation in QAPI meetings was important and stated, "Thought someone else was taking care of it." 5. Interview on 9/19/24 at 11:05 a.m. with administrator A and director of nursing (DON) C regarding pharmacy services and QAPI meetings revealed it was their expectation for the pharmacy to be involved in QAPI meetings and to report any monitoring or concerns to QAPI. 6. Review of the provider's 9/16/24 Clinical Pharmacist job description revealed some of their essential functions were to participate in quality improvement projects and to act as a resource in their area of specialty. 7. Review of the provider's 4/26/23 Quality Assurance and Performance Improvement Policy revealed: *"Guiding Principles: 2. In our organization, QAPI includes all employees, all departments and all services provided." *"Team members (Leaders or designee from each dept/service)" -A leader and/or designee from the pharmacy department was not listed as a member of that team. *"Meetings (bi-monthly)" *The pharmacy department was not included as	C1300		

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C1300	Continued From page 20 part of the QAPI standing agenda or annual review. 8. Review of the parent hospital's November 2022 Quality Assessment and Performance Improvement policy revealed: *"Policy Statement: It is the responsibility of the Board of Trustees, Boards of Directors, Medical Staff, and caregivers to participate in and cooperate with quality assessment and performance improvement program activities." *"D. Responsibility for Performance Improvement: Every caregiver, medical and allied health staff member, Board member and volunteer is responsible, individually and collaboratively, for improvement in the performance of the Hospital's services and functions." -"D. 2. Management Staff: a. By directing performance improvement activities in their respective units/department/clinic/program. b. By serving as chairs, team leaders, or members of committees, subcommittees, teams, and/or task forces related to performance improvement activities." *"K. Department/Program Activities: 3. Department, program, and service line directors will be responsible for the completion, maintenance, and reporting of metrics/indicators."	C1300		
C1616	SOCIAL SERVICES CFR(s): 485.645(d)(4) Social Services (§483.40(d) of this chapter). " §483.40(d) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident. This STANDARD is not met as evidenced by:	C1616	SOCIAL SERVICES The Senior Director of Case Management has overall responsibility for compliance with this tag. Service level agreement was collaborated between Case Management/Social Worker leadership and the facility Administrator to provide Master of Social Work (MSW) oversight with RN Case Manager. Social Service designee position was eliminated from Monument Health Custer. RN Case Manager will provide all clinical assessments with	10/03/2024

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C1616	Continued From page 21 Based on document review, interview, and policy review, the provider failed to ensure one case manager (CM) (L) and one social worker designee (SWD) (B) had ongoing support and monitoring by a licensed social worker (LSW) since June of 2023. Findings include: Review of the provider's LSW consultant reports from 10/25/22 through 6/29/23 revealed: *LSW S had consulted with both the case manager (CM) L and social worker designee (SWD) B on a quarterly basis to review patient charts and discuss any concerns/questions that they might have. *There were no LSW consultant reports provided after 6/29/23 for review. -That had been approximately 15 months with no documentation to support a LSW had been working with CM L and SWD B per regulation. Review of the provider's South Dakota Board of Social Work Examiners form revealed: *On 3/8/24 LSW H had signed the form to support her role as the consultant for SWD B effective 3/4/24. *That consulting relationship had not been put in place until nine months after the last consult report that was submitted by LSW S. *No other agreement was provided to support who was the LSW consultant during those nine months. Interview on 9/19/24 at 11:10 a.m. with administrator A and director of nursing (DON) C revealed: *LSW S resigned shortly after her last visit to the facility and LSW H was the new consultant for CM L and SWD B. *They were not aware there was no LSW	C1616	collaboration with MSW for Social Services documentation review, patient abuse/neglect investigations, review of grievances. The purpose of the service line agreement is to establish a collaborative partnership between the Monument Health Critical Access Hospital teams and the Rapid City Care Management department related to the support for Social Services. Leaders from Rapid City Care Management, MSW, RN Case Manager, Director of Nursing and Market President from Custer Hospital all educated on service line agreement on 10/03/2024. Monitoring: Documentation of collaboration will be conducted with each review by RN Case Manager and MSW which will be completed at least monthly and as needed. These cases of documentation will be reported to QAPI and the Advisory Board monthly by the RN Case Manager identifying compliance with completing reviews at least quarterly.	

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C1616	Continued From page 22 consultant reports since 6/29/23 and agreed there should have been. *Their LSW consultants came and were assigned from their parent provider. *Administrator A stated: "I would just expect that everyone would meet the needs of patients like they are supposed to." Observation and interview of 9/19/24 at 1:19 p.m. with administrator A regarding a Service Level Agreement form revealed: *The document stated: -"Service Level Agreement: For partnership with [provider name] Long Term Care (LTC) and [provider name] Critical Access Hospitals (CAH). -The purpose of this Service Level Agreement (SLA) is to establish a collaborative partnership between [provider name] LTC and CAH teams and a Licensed Social Worker to support expectations and compliance. We believe that through intentional development of this partnership we can better achieve goals, build collaboration, promote continued growth and development of both and manage our patient's experience with the services provided." -"Approach: --It will include joint collaboration between the [provider name] LTC and CAH teams and a Licensed Social Worker to support expectations and compliance. We believe that through intentional development of this partnership we can better achieve goals, build collaboration, promote continued growth and development of both and manage our patient's experience with the services provided." *She had just received that document from the parent provider. -The form was signed and dated by the parent provider's critical access hospital leadership staff	C1616		

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C1616	Continued From page 23 on 5/8/24. -There were two lines for the care management leadership to sign the form but they were blank and unsigned. *Administrator A stated: -"I just got that form [parent provider's name] and I had no idea it existed until now." -"Those blank lines is where I was supposed to have signed one of them." -"I had no idea we were not meeting the LSW consultant requirements until now." Interview on 9/19/24 at 1:23 p.m. with clinical quality coordinator N and accreditation specialist O revealed: *Neither of them had been aware of the Service Level Agreement form. *Clinical quality coordinator N stated: -"No, I didn't know anything about this agreement and it should have been discussed in our quality meetings for sure." -"Any change like this for our facility should be discussed in quality and I have no recollection of this being reviewed at all." *Accreditation specialist O confirmed that the provider should have had LSW consulting quarterly. -The consultations could have been virtually or in person. Interview on 9/19/24 at 1:45 p.m. with DON C regarding the Service Level Agreement revealed: *He had not been aware of the agreement until they just received it that afternoon. *He stated: -"I even checked my emails and I had no notifications regarding this agreement." -"Yes, I should have been made aware. If it affects my patients, absolutely."	C1616		

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C1616	Continued From page 24 Interview on 9/19/24 at 1:46 p.m. with CM L and SWD B revealed: *They had worked in collaboration together to ensure the patients' needs were met during their stay and upon discharge. *They confirmed LSW S: -Was no longer employed with the parent provider and her last consultation with them had been on 6/29/23. -Had informed them on 6/29/23 that would have been her last consultation with them. *They had reached out to LSW H after the resignation of LSW S for further guidance from her. *LSW H had told them she did not have a current plan in place, but until further notice, she would have been their consultant. *Since 6/29/23: -No one had called or set-up a meeting with them for consultation. -They would reach out to other LSWs that they knew personally for guidance. -They had not heard from LSW H until recently. She had informed them that she would be coming for a visit in October sometime. *They: -Were not aware of any Service Level Agreement and since it involved them, they would have expected notification of this. -Agreed they were not meeting the LSW consultation requirements and should have been. *To their knowledge, there was no formal LSW consultation policy, just the signed agreement.	C1616		