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MONUMENT HEALTH RAPID CITY HOSPITAL	353 FAIRMONT BLVD RAPID CITY, SD 57701

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A 000	INITIAL COMMENTS A complaint health survey for compliance with 42 CFR Part 482, Subparts A-D; and Subsection 482.66 requirements for hospitals was conducted from 9/19/23 through 9/20/23. Areas surveyed included patient abuse, neglect, and patient admission, transfer, and discharge rights. Monument Health Rapid City Hospital was found not in compliance with the following requirements: A115, and A431.	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 the provider's submitted South Dakota Department of Health (SD DOH) incident report review, medical review, and interview the provider failed to ensure one of one sampled patient (1) had received a repeat serum (human choronic gonadotropin) HCG qualitative test. Findings include: 1. Review of the 8/3/23 provider-submitted event report to the SD DOH incident report revealed: *On 7/18/23 patient 1 was seen in the emergency department (ED) for a ruptured ectopic pregnancy. *She was evaluated previously in the ED on 7/3/23 when an HCG (human chorionic gonadotropin) qualitative lab test (pregnancy test) was ordered by the physician with negative results reported. *That test result was recorded incorrectly in the EMR and the results were actually positive. *"Had it been identified sooner that the patient	A 115	Emergency Services Medical Director reviewed the case and worked with Director of Quality, Safety, and Risk Management to create a process to review female patients with an ordered pregnancy test and a return to the ED within 30 days to ensure a repeat pregnancy test was ordered. If a case falls out of compliance the Emergency Services Medical Director will complete a review of the case and provide follow-up to the Emergency Services provider. Education regarding the process review will be provided to the Emergency Services physicians by 10/31/23. Any Emergency Services physician on leave will be required to complete education prior to the first worked shift. Emergency Services Medical Director will monitor education completion. Monitoring: Quality, Safety, Risk Management Director or designee will review all Emergency Department female patients with an ordered pregnancy test to ensure a correct HCG lab was	10/31//2023

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

Julie Sime | V.P. Quality, Safety RM | 10/25/23

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 115	Continued From page 1 was pregnant, there is possibility that the pregnancy would have been managed medically only and surgery could have been avoided". Review of patient 1's EMR revealed: *She was seen on 7/3/23 at the ED for vaginal spotting and abdominal pain. *She informed the medical staff she suspected she could have been pregnant. *A serum HCG qualitative lab test was ordered by the physician with negative results reported by the laboratory (lab). *She returned to the ED on 7/13/23 with the same symptoms as she had presented to the ED initial visit on 7/3/23 but her pain had worsened and she had used all of her prescribed pain medication. *The independent interpretation shows a CAT (Computerized Tomography) scan of her abdomen was negative for acute life-threatening findings. *A repeat pregnancy test had not been ordered by the physician. *The incorrect negative pregnancy test result performed on 7/3/23 was referenced on 7/13/23 when treatment was provided. Refer to A431	A 115	documented and if there was a return to the ED in 30 days, that a repeat pregnancy test was completed. Any fallouts will be reviewed by the Emergency Services Medical Director. Monitoring will occur until 100% compliance is sustained for 3 consecutive months. Results will be reported monthly to the Vice President of Quality, Safety, Risk Management, Vice President of Lab, and Medical Staff.	
A 431	MEDICAL RECORD SERVICES CFR(s): 482.24 The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital. This CONDITION is not met as evidenced by: Based on the provider's submitted South Dakota	A 431	Director of Laboratory Services, Laboratory Manager and Supervisor started a Plan Do Check Act (PDCA) to review the process of all manual entry laboratory tests on 7/24/2023. During the PDCA, it was determined to improve process controls by requiring two persons reviewing and resulting manual entries. The completed PDCA was signed by Laboratory Director, Quality Manager and Manager on 8/11/2023. The Director of Laboratory	10/31//2023

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A 431	Continued From page 2 Department of Health (SD DOH) incident report review, medical record review, interview, and policy review, the provider failed to ensure one of one laboratory technician (tech) (C) had recorded accurate pregnancy test results in one of one sampled patient (1's) electronic medical record (EMR) who sought treatment in the emergency department (ED) which resulted in the following delays: *The patient receiving medical emergency treatment for an ectopic pregnancy (when a fertilized egg grows outside of the uterus in the fallopian tubes). *Emergency surgery to remove the ruptured right fallopian tube. Findings include: 1. Review of the 8/3/23 provider-submitted event report to the SD DOH revealed: *On 7/18/23 patient 1 was seen in the emergency department (ED) for a ruptured ectopic pregnancy. *She was evaluated previously in the ED on 7/3/23 when an HCG (human chorionic gonadotropin) qualitative lab test (pregnancy test) was ordered by the physician with negative results reported. *That test result had been recorded incorrectly in the electronic medical record (EMR) and the results were positive. *"Had it been identified sooner that the patient was pregnant, there is possibility that the pregnancy would have been managed medically only and surgery could have been avoided". Review of patient 1's EMR revealed: *She was seen on 7/3/23 in the ED for vaginal spotting and abdominal pain. *She informed the medical staff she suspected	A 431	Services requested to add to EPIC, the electronic medical record for all manual lab result entries, to require a co-signature by a second Laboratory Technician. The EPIC build for this lab entry requirement went live on 8/9/2023. Director of Laboratory Services and leadership team educated all staff on the manual entry process change through 1:1 rounding, huddles, and email on 8/9/2023. Any caregivers on leave will be required to complete education prior to the first worked shift. Lab Information System Policy was approved to reflect new process change with RCH manual lab entries into EPIC system on 9/20/2023. Director of Laboratory Services developed education regarding serious adverse event reporting to emphasize timeliness of reporting. Education to all laboratory leaders and technicians on the Serious Adverse Events policy and the timeliness of reporting was conducted by the Director of Laboratory Services or designee by 10/31/2023. Any caregivers on leave will be required to complete education prior to the first worked shift. Monitoring: Laboratory Quality Program Manager or designee will complete 20 manual laboratory entry audits weekly until 100% compliance is sustained for 3 consecutive months. This data is summarized and reported out monthly	

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A 431	Continued From page 3 she could have been pregnant. *A serum HCG qualitative lab test was ordered by the physician with negative results reported by the laboratory (lab). *A transvaginal ultrasound was performed that reported the following: 1. "Abnormally thickened endometrial stripe measuring 2.9 cm [centimeters]. 2. Indistinct vaguely masslike area in the right adnexa [the region adjoining the uterus that contains the ovary and fallopian tube] appears to be separate from the right ovary. Unclear if this is nonperistalsing [non-moving] bowel versus mass lesion. Evaluation with pelvis MRI (magnetic resonance imaging) recommended. 3. Unremarkable appearance of both ovaries with normal ovarian Doppler exam." *She was treated and released with home instructions to follow up with her primary care physician for further testing. *She returned to the ED on 7/13/23 with the same symptoms as she had on the 7/3/23 initial ED visit but her pain had worsened, and she had used all of her prescribed pain medication. *The independent interpretation showed a CAT (Computerized Tomography) scan of her abdomen was negative for acute life-threatening findings. *A repeat pregnancy test was not ordered by the physician. *The incorrect negative pregnancy test result from 7/3/23 was referenced on 7/13/23 when treatment was provided. *She was discharged home to follow up with her primary care provider (PCP) as previously scheduled. *On 7/18/23 she returned to the ED due to worsened pain and increased vaginal bleeding. *A follow-up appointment with her PCP revealed	A 431	by the lab quality program manager or designee to Laboratory Supervisor, Manager, Director, Pathology Medical Director and Vice President of Rapid City Market.	

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an elevated HCG level and possible ectopic pregnancy.
*A repeat HCG lab test was performed with positive results.
*A ruptured ectopic pregnancy was discovered which required an emergency laparoscopic surgical procedure to remove her right fallopian tube on 7/18/23.

Interview on 9/19/23 at 11:45 a.m. with lab tech specialist N and lab tech manager F revealed:
*As a result of patient 1's incorrect test result in the EMR, the laboratory had implemented an update to the EMR system for entering the lab results.
*The new dual verification process included a second lab staff to complete the following:
-Review the test kit results with the lab tech conducting the test to confirm the lab results.
-Check the EMR to ensure the lab tech had entered the correct lab results into the EMR and those results matched the test kit results.
-Initial in the EMR that the dual verification process had been completed and those test results were accurate.

Review on 9/19/23 at 12:10 p.m. of the laboratory test kit results logbook revealed:
*A 7/3/23 log entry that had identified patient 1 with a "+" (positive) result of her pregnancy test with lab tech C's initials next to it.

Interview on 9/19/23 at 4:45 p.m. with lab tech C and lab tech manager F regarding patient 1's 7/3/23 pregnancy test results revealed:
*The lab tracked the test kit results using a paper logbook with handwritten results documented by the lab techs.
*Lab tech C confirmed he was the staff member

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who performed the pregnancy test for patient 1 on 7/3/23 and recorded the positive result in the logbook.
*He wrote the positive test result onto a label for patient 1 and then transferred the result to the EMR.
*The test result was recorded by him in the patient's EMR and was documented as negative, which was incorrect.
*He estimated the time between handwriting patient 1's test results into the logbook and recording those test results into the EMR had been "less than 60 seconds".
*"I made a mistake. I don't know what was going through my head."
*In his experience, most pregnancy test results had resulted in negative findings.
*He thought it had been "muscle memory" (habit) that had caused him to record the incorrect test result in the EMR.
*Lab tech manager F revealed:
-That incorrect lab test result had been brought to her attention by an obstetric physician on 7/19/23.
-She checked the logbook against the patient's EMR and confirmed the error in the EMR, the test performed should have been recorded as a positive result and had been incorrectly recorded as negative.
-She instructed lab tech specialist N to make a note to correct the pregnancy test result in patient 1's EMR to reflect it had been a positive test result on 7/3/23.
-That EMR correction had been made on 7/19/23 over two weeks after the pregnancy test had been performed.
*Lab tech manager F reported she had implemented 20 audits each week to ensure accurate test results had been conducted and reported in the patient's EMR.

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A 431	Continued From page 6 *Prior audits conducted by the lab quality program manager J had been ineffective in capturing measurements of whether the new dual verification process had reduced or eliminated the problem of human entry error. *Documentation of audits completed by lab tech manager F were requested. Those audits that were provided had just begun on 9/19/23, which was the day the survey had begun. *When asked why those audits had not started earlier, lab tech manager F stated "It was on my things to do list, but I had not gotten to it until this morning." Interview on 9/20/23 at 1:05 p.m. with director of lab services G regarding patient 1's incorrect test results revealed: *The lab had completed an internal investigation and a root cause analysis. *On 8/9/23 they started a dual verification system for test kit results that were updated and implemented into the EMR computer system. *Audits were to have been conducted to ensure the dual verification process was working in reducing or eliminating error in reporting patient lab test results. *Lab quality program manager J had begun audits to gather data, but when the data results were analyzed, the data was not effective to show the lab test results had been cross-matched from the lab logbook and within the EMR to ensure accuracy. *She confirmed "Our team hasn't sat down together to ensure everyone had been on the same page regarding what needed to be measured to validate the dual verification process had been effective." *The lab staff had been provided verbal education about the new dual verification process.	A 431		

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*Lab tech manager F had started the newly identified audits on 9/19/23, which was two months after they were informed of the inaccurate lab test results for patient 1.
*That had been an "atypical" situation that she thought could have been avoided had they taken a team approach with regard to the discovery of the lab testing error for patient 1.
*A request was made for the provider's updated policy and procedure for a two-person verification of patient lab test kit results.
-She was unaware if the policy had been revised or who had been responsible for updating the policy.

Interview on 9/20/23 at 4:30 p.m. with performance engineer H and quality, safety, risk management manager E revealed:
*The lab staff had been informed of the lab test error for patient 1 on 7/19/23.
*Normally the quality team would have been involved in completing a root cause analysis within 5 days of receiving the notification of an incident, which would have been on 7/24/23.
*She had received notification of patient 1's incident on 8/1/23 when the incident had been entered into their risk connect system by an obstetrician.
*The lab department had not followed the notification process for an adverse event.
*Because of the lack of notification, the quality and risk management team had not been involved with guidance on how to proceed with an action plan that should have been started within the 5-day time frame.

Review of the provider's May 2023 Serious Adverse Events policy revealed:
*"C. Reporting Process:

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-1. Serious adverse events [SAE] are to be reported as soon as possible after the event is discovered. If an employee questions whether an event is SAE. he/she should call their Department Director, the Vice President of Quality, Safety, and Risk Management, or Associate General Counsel for assistance and clarification.
-2. Reporting: Administration and Medical staff from involved areas(s) will be informed of the Serious Adverse Event if they have not previously been notified.
-3. Event Reports: The Serious Adverse Event should also be reported in the appropriate patient event reporting system."
*"E. Root Cause Analysis: A Root Cause Analysis [RCA] will begin within 5 business days of event notification and be completed within 45 days of discovery of the sentinel event. The facility Risk Management designee or the Vice President of Quality, Safety, and Risk Management will facilitate the Root Cause Analysis using a multidisciplinary team."

Interview on 9/20/23 at 9:10 a.m. with registered nurse (RN) L regarding recommending a repeat pregnancy test for ED patients revealed:
*She had worked in the ED for 29 years.
*ED patients that had returned ten days later after an initial pregnancy test was negative with the same or worsen chief complaint of abdominal pain, she would recommend to the ED provider to repeat a pregnancy test.
*She had a good working relationship with the providers in the ED and they would collaborate during patient care.

Interview on 9/20/23 at 9:30 a.m. with RN K

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A 431	Continued From page 9 regarding recommending a repeat pregnancy test for ED patients revealed: *She had worked in the ED for four years. *She felt that a repeat pregnancy test for a patient with the same or worsened abdominal pain ten days after a negative test would have been the best practice. Interview on 9/20/23 at 12:30 p.m. with medical director (MD) D regarding repeat pregnancy tests for ED patients revealed: *He had been the medical director for the ED for two years and had worked in the ED for 15 years. *MD D would not have repeated a pregnancy test for a patient with the same or worsened abdominal pain if the first test was negative ten days earlier. *He would have trusted the negative result from the first pregnancy test and moved forward with additional testing. *MD D felt in hindsight a repeat pregnancy test would have confirmed the pregnancy. *He had reviewed the case and felt that the treatment was appropriate. *He would not repeat the pregnancy test if a similar situation had been presented to the ED. *ED medicine was designed to decide if a patient's chief complaint was life-threating or not.	A 431		

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A 000	INITIAL COMMENTS An onsite revisit survey was conducted on 11/2/23 for compliance with 42 CFR Part 482, Subparts A-D; and Subsection 482.66 requirements for hospitals for all previous deficiencies cited on 9/20/23. All deficiencies have been corrected and no new non-compliance was found. Monument Health Rapid City Hospital was found in compliance with all regulations surveyed.	A 000		

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