

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

PRINTED: 09/05/2024
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 431327	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/29/2024
NAME OF PROVIDER OR SUPPLIER ST MICHAEL'S HOSPITAL - CAH			STREET ADDRESS, CITY, STATE, ZIP CODE 410 W 16TH AVE TYNDALL, SD 57066	
(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
C 000	INITIAL COMMENTS	C 000	1. On 8/28/2024, upon discovery of the key in the anesthesia cart the key was removed and placed in the procedure room lock box, which is locked in the hospital pharmacy. The bottle of sevoflurane was removed from the anesthesia cart and locked in the medication cart.	10/7/2024
C1016	<p>PATIENT CARE POLICIES CFR(s): 485.635(a)(3)(iv)</p> <p>[The policies include the following:]</p> <p>(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use. This STANDARD is not met as evidenced by: Based on observation, interview, and policy review, the provider failed to ensure only authorized personnel had access to medications stored in two of two carts (anesthesia cart and medication cart) in one of one procedure room. Findings include:</p> <p>1. Observation and interview on 8/28/24 at 9:00 a.m. with material purchasing technician B in the procedure room revealed: *The procedure room was open due to another surveyor completing survey tasks. *The material purchasing technician was asked if the red tool chest was used for medication</p>	C1016	<p>2.A process has been created to maintain the key to the medication cart in the hospital pharmacy in the "procedure room lock box". This box is locked in the pharmacy's controlled substance cabinet. The procedure day RN removes this box on procedure days and gives to the nurse anesthetist. The key will be monitored by the procedure day RN and the hospital pharmacist, on procedure days, to ensure the key is returned to the lock box in the hospital pharmacy. Access to the hospital pharmacy is given to authorized personnel, per policy, to the pharmacist and nurses. The sevoflurane bottle is locked in the medication cart and access to the medication cart is by getting the key from the procedure room lock box. Education on the process change will be provided to the nurse anesthetist, procedure day RNs, and pharmacists by October 7th, 2024. Education will be monitored by the DON. Pharmacy and Therapeutic committee met September 16, 2024, and approved an updated policy to reflect process change for key to the procedure room medication cart.</p> <p>3. See next page.</p>	

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

TITLE

(X6) DATE

Ashli Danilko

CEO

9/12/2024

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.

SEP 19 2024

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C1016	<p>Continued From page 1 storage.</p> <p>*She then opened the unlocked anesthesia cart drawer and removed a set of keys stored in a plastic cup.</p> <p>*She then opened the red tool chest (medication cart) located next to the anesthesia machine.</p> <p>*The certified nurse anesthetist stored the medication cart key in the anesthesia machine drawer.</p> <p>*Certified nursing assistants, housekeeping, and maintenance had access to the procedure room.</p> <p>*She was not aware she or the above listed staff should not have access to medications.</p> <p>*The procedure room door was secured with a punch key lock which was the normal practice.</p> <p>Observation on 8/28/24 at 9:00 a.m. in the procedure room confirmed:</p> <p>*In the anesthesia cart was one bottle of sevoflurane (a volatile anesthetic that provides hypnosis, amnesia, and analgesia during surgical procedures).</p> <p>*The medication cart had the following medications inside of it:</p> <ul style="list-style-type: none"> -Xylocaine 20 milliliter (ml) one vial. -Normal saline 0.9 percent (%) six syringe flushes. -Nitroglycerin 0.4 milligrams (mg) tabs one vial. -Ondansetron 4 mg/2 ml one vial. -Glycopyrrolate 0.2 mg/ml two vials. -Ketorolac tromethamine 30 mg/ml one vial. -Naloxone 0.4 mg/ml one vial. -Ephedrine sulfate 50 mg/ml one ampule. -Diphenhydramine 50 mg/ml one vial. -Lidocaine 50 mg/5 ml one vial. -Hydralazine 20 ml one vial. -Phenylephrine 10 mg/1 ml two vials. -Labetalol 100 mg/20 ml one vial. -Adrenalin 1 mg/ml one vial. 	C1016	<p>3. As a result of the process changes, there are several QAPI measurements. The first is the QAPI measure, percent of times the key was appropriately locked in the hospital pharmacy in the procedure room lock box. A second QAPI measurement is also checking that the sevoflurane is located in the locked medication cart pre and post procedure day. Measurement for both of these measures will occur monthly during the controlled substance inventory check and on procedure days. Data will be reported monthly to the quality committee by the DON until the QAPI has been 100% for 6 continuous months. Additional oversight includes dashboard review with the medical staff and hospital board of directors.</p>	10/7/2024

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C1016	<p>Continued From page 2</p> <ul style="list-style-type: none"> -Epinephrine 1 mg/ml one vial. -Flumazenil 0.5 mg/5 ml one vial. -Bupivacaine 0.25% 10 ml one vial. <p>Interview on 8/28/24 at 9:15 a.m. with director of nursing (DON) A and pharmacist C confirmed:</p> <ul style="list-style-type: none"> *The keys to the medication cart should not have been stored in the unlocked anesthesia cart. *Medications stored in the procedure room would have been accessible to unauthorized personnel and should have been securely stored. *The DON and pharmacist C were not aware the anesthetist had his own set of keys. *A secure place to store the anesthesia medication keys would need to be determined. <p>Interview and review on 8/29/24 at 12:16 p.m. with pharmacy manager D of the provider's November 2023 Medications Located Outside the Pharmacy policy confirmed:</p> <ul style="list-style-type: none"> *All areas where medications were stored should have been locked at all times. *The policy had not addressed that medications should not have been assessable to unauthorized individuals. *She was not aware the anesthesia provider had a set of keys. *The keys to the medication cart should not have been stored in the unlocked anesthesia cart for safety reasons. *Medications stored in the procedure room carts would have been accessible to unauthorized staff (certified nursing assistants, housekeeping, and maintenance). 	C1016			

South Dakota Department of Health

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NAME OF PROVIDER OR SUPPLIER ST MICHAEL'S HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 410 W 16TH AVE TYNDALL, SD 57066
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S 000	Compliance/Noncompliance Statement A licensure survey for compliance with the Administrative Rules of South Dakota, Article 44:75, Hospital, Specialized Hospital, and Critical Access Hospital Facilities, was conducted from 8/27/24 through 8/29/24. St. Michael's Hospital was found not in compliance with S433.	S 000	1. St. Michael's has revised their admission packet with the missing components from the administrative rule, 44:75:15:03, including the required admission agreement signature form. These revised packets and the agreement form were put into effect with admissions on or after 9/12/24.	10/7/2024
S 433	44:75:15:03 Facility to Provide Information-Adm Agreement A signed and dated admission agreement between the patient or the patient's legal representative and the facility shall include subdivisions (1) to (8), inclusive, of this section. The patient or patient's legal representative and the facility shall complete the admission agreement before or at the time of admission and before the patient has made a commitment for payment for proposed or actual care. The agreement may not include ambiguous or misleading information and may not be in conflict with this chapter. The agreement shall be printed for ease of reading by the patient. If the agreement exceeds three pages, it shall contain a table of contents or an index of principal sections. Any change in the information shall be given to the patient or the patient's legal representative as a signed and dated addendum to the original agreement. This Administrative Rule of South Dakota is not met as evidenced by: Based on record review, interview, Swing Bed Program Information sheet review, and hospital admission packet review, the provider failed to ensure five of five (1, 2, 3, 4, and 5) sampled swing bed patients had received information on: *Services available in the facility and the charges for those services.	S 433	2. The Health Unit Coordinator will review every swing bed admission for a proper signed and dated admission agreement that includes subdivisions (1) to (8) between the patient/legal representative and St. Michael's Hospital Avera. Education on this process change will be provided to nurses and health unit coordinators by October 7, 2024. Education will be monitored by the DON. 3. The QAPI data, percentage of admission agreements signed/dated, will be reported monthly by the DON on the QAPI dashboard to the quality committee until the QAPI has been 100% for 6 continuous months. Additional oversight includes dashboard review with the medical staff and hospital board of directors.	

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

Ashli Danilko

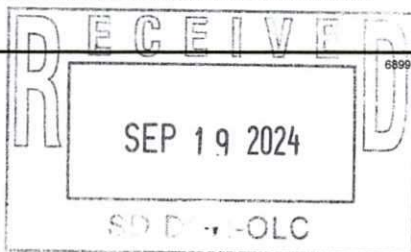
STATE FORM

TITLE

CEO

(X6) DATE

9/12/2024



TMQG11

If continuation sheet 1 of 3

South Dakota Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 48584	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/29/2024
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NAME OF PROVIDER OR SUPPLIER ST MICHAEL'S HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 410 W 16TH AVE TYNDALL, SD 57066
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S 433	<p>Continued From page 1</p> <p>*Services offered for which the patient may not have been charged and services the patient would have been charged. *How patients can protect their personal funds. *How to apply for and use Medicare. *The address and telephone number for the nearest United States Social Security Administration office. *The provider's bed-hold policy, length of time held, and readmission rights. *The responsibilities for self-administration of medications. *The availability of survey results and plan of correction upon request. Findings include:</p> <p>1. Review of patients' 1, 2, 3, 4, and 5's medical record revealed the information listed above was not included within the following documents: *The signed Consent - Admission form in the medical record for patients 1, 2, 3, 4, and 5. *The Swing Bed Program Information sheet provided to patients when admitted to swing bed. *The hospital admission packet.</p> <p>Interview and review of the Administrative Rules of South Dakota 44:75:15.03 (S433) on 8/29/24 at 10:30 a.m. with director of nursing A confirmed upon admission the swing bed patients had not received information on: *Facility available services and charges. *Services the patient was responsible for paying and services that had no charge. *How to protect their personal funds. *The address for the nearest United States Social Security Administration office. *The provider's bed hold policy. -The provider had not done bed holds in the past, but there was a potential they could. *The availability of survey results upon request.</p>	S 433		

South Dakota Department of Health

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NAME OF PROVIDER OR SUPPLIER ST MICHAEL'S HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 410 W 16TH AVE TYNDALL, SD 57066
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NAME OF PROVIDER OR SUPPLIER ST MICHAEL'S HOSPITAL - CAH	STREET ADDRESS, CITY, STATE, ZIP CODE 410 W 16TH AVE TYNDALL, SD 57066
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E 000	<p>Initial Comments</p> <p>A recertification health survey for compliance with 42 CFR Part 485, Subpart F, Subsection 485.625, Emergency Preparedness, requirements for Critical Access Hospitals, was conducted on 8/27/24. St. Michael's Hopsital - Cah was found in compliance.</p>	E 000		

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

TITLE

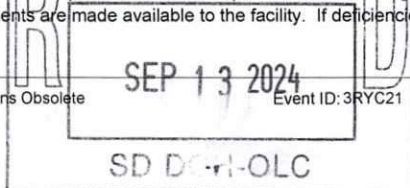
(X6) DATE

Ashli Danilko

CEO

9/12/2024

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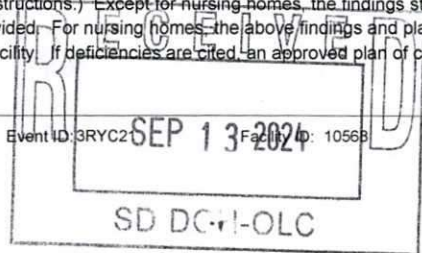
NAME OF PROVIDER OR SUPPLIER ST MICHAEL'S HOSPITAL - CAH	STREET ADDRESS, CITY, STATE, ZIP CODE 410 W 16TH AVE TYNDALL, SD 57066
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K 000	<p>INITIAL COMMENTS</p> <p>A recertification survey was conducted on 8/27/24 for compliance with 42CFR 485.623(d) (1), requirements for critical access hospitals. St. Michael's Hospital - Cah (Bldg 01) was found in compliance.</p>	K 000		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Ashli Danilko	TITLE CEO	(X6) DATE 9/12/2024
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K 000	INITIAL COMMENTS A recertification survey was conducted on 8/27/24 for compliance with 42CFR 485.623(d) (1), requirements for critical access hospitals. St. Michael's Hospital - Cah (Bldg 02) was found in compliance.	K 000			

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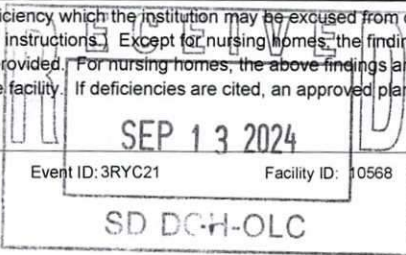
Ashli Danilko

TITLE
CEO

(X6) DATE

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Event ID: 3RYC21

Facility ID: 10568

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NAME OF PROVIDER OR SUPPLIER ST MICHAEL'S HOSPITAL - CAH			STREET ADDRESS, CITY, STATE, ZIP CODE 410 W 16TH AVE TYNDALL, SD 57066	
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K 000	INITIAL COMMENTS A recertification survey was conducted on 8/27/24 for compliance with 42CFR 485.623(d) (1), requirements for critical access hospitals. St. Michael's Hospital - Cah (Bldg 03) was found in compliance.	K 000		

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