

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

PRINTED: 12/17/2025
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 431300 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 12/04/2025 |
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| NAME OF PROVIDER OR SUPPLIER MADISON REGIONAL HEALTH SYSTEM | STREET ADDRESS, CITY, STATE, ZIP CODE 323 SW 10TH ST MADISON, SD 57042 |
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| C 000 | <p>INITIAL COMMENTS</p> <p>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 12/02/25 through 12/04/25. Madison Regional Health System was found not in compliance with the following requirements: C914 and C1140</p> | C 000 | | |
| C 914 | <p>MAINTENANCE</p> <p>CFR(s): 485.623(b) , 485.623(b)(1)</p> <p>The CAH has housekeeping and preventive maintenance programs to ensure that--</p> <p>(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, record review, manufacturer's instructions for use (IFU) review, and policy review, the provider failed to ensure: *Acceptance testing (test by biomedical technician when a new piece of medical equipment is received) had been performed on one of one Deluxe Professional Stone Heater (warming device used to heat massage stones). *Temperatures had been documented for two of two pieces of equipment (Deluxe Professional Stone Heater and towel warmer) located in the message therapy room.</p> <p>Findings include:</p> <p>1. Observation and interview on 12/4/25 at 10:49 a.m. with director rehab services J, director of quality and infection control (IC) B revealed: *There was a Deluxe Professional Stone Heater</p> | C 914 | <p>The Deluxe Professional Stone Heater and the Towel Warmer have been added or verified the equipment is already on the Biomed equipment listing, tagged, and scheduled for maintenance checks. Our biomed vendor will be responsible for ensuring the maintenance checks are completed on schedule. The hospital does receive a report from the vendor on the compliance and timeliness of maintenance checks on all equipment the vendor is responsible for. This was completed on 12-12-25. Policies for temperature monitoring and tracking have been updated. Staff competency has been completed and evidenced by their signature on the policy page. A log sheet has been created for verification of temperature with each hot stone usage and temperature tracking for the towel warmer. A calibrated thermometer is also easily accessible for both pieces of equipment. The policy for each piece of equipment has also been clarified on the required temperature requirements. The Director of Rehab Services is responsible for ensuring the log sheets are being filled out. Monitoring of log sheets will take place for six months. Results of the log sheets will be reported to the quarterly Quality committee. Reports from the quality committee are given to the Board of Directors at the next Board Meeting following the committee meeting. The deficiency is resolved as of 12-26-25.</p> | 12/26/25 |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Teresa Mallett</i> | TITLE CEO | (X6) DATE 12/31/2025 |
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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 914 | <p>Continued From page 1</p> <p>located in the corner of the room without an equipment testing verification sticker for when the last inspection date was.</p> <p>*They confirmed there was no sticker stating the date of the last inspection of the stone warmer.</p> <p>*There was a towel warmer located by the sink in the room.</p> <p>*There was not a temperature log for the stone heater or the towel warmer.</p> <p>*There was not a thermometer in either piece of equipment.</p> <p>*They stated licensed massage therapist I tracked the temperature of the stone heater and the towel warmer but had not documentation to verify the temperatures in a temperature.</p> <p>Interview on 12/4/25 at 11:50 a.m. with director of quality and IC B revealed the field service technician III K if the stone warmer did not have a sticker they would have needed to perform an initial inspection. He did not know who performed the initial inspection.</p> <p>Interview on 12/4/25 at 12:00 p.m. with licensed massage therapist I revealed:</p> <p>*Water temperature should have been between 120 degrees Fahrenheit (F) to 140 degrees Fahrenheit.</p> <p>*She stated she would have tested the water temperature twice during a treatment but would not have documented the temperature.</p> <p>Interview on 12/4/25 at 1:20 p.m. with field service tech III K revealed he:</p> <p>*Thought an acceptance test had been performed on the stone warmer.</p> <p>*Was not able to locate a record of the initial inspection to prove it had been performed.</p> <p>*The stone warmer would have needed an</p> | C 914 | | |
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| C 914 | <p>Continued From page 2</p> <p>acceptance test but not an annual evaluation.</p> <p>Review of the September 2010 Massage Therapy Journal article (Don't) Feel the Burn: Hot Stone Massage revealed: *The only safe way to heat stones in water would have been to accurately control the temperature of the water." *A calibrated thermometer should have been used to test the temperature of the water instead of relying only on the thermostat of the warmer.</p> <p>Review of the Message Stone Heater IFU revealed an accurate thermometer should have been used to measure the water temperature in the water reservoir.</p> <p>Review of the provider's July 2018 Massage Therapy Hot Stones policy revealed water temperatures should have been checked to ensure water temperatures between 110 degrees F to 130 degrees F. *The policy did not support how to check the temperatures, how often the temperatures should have been checked, or define a process to support the staff had checked the temperature to ensure it remained within that range.</p> <p>Review of the provider's May 2024 Medical Equipment Management Plan revealed an incoming inspection to include safety, operational, and functional test should have been performed on all medical equipment entering the facility and prior to use.</p> <p>Review of the provider's November 2023 Blanket Warmer/Fluid Warmer policy revealed: *The temperature should have been no greater than 130 degrees F.</p> | C 914 | | |

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| C 914 | Continued From page 3 *Temperatures should have been monitored daily. *The external temperature display needed to be compared to the internal temperature. *There was no process within the policy to support how they supported the temperature was checked, how often it should have been checked, and ensured it was within the required temperature range. | C 914 | | |
| C1140 | SURGICAL SERVICES CFR(s): 485.639 If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section. This CONDITION is not met as evidenced by: Based on observation, record review, interview, manufacturer's instructions for use (IFU) review, and policy review, the provider failed to: *Follow manufacturer's IFU for Revital-Ox Resert High Level Disinfectant used for high level disinfection for three of three endocavity (within the body) vaginal probes. *Document the disinfection time, solution temperature, vaginal probe number, and patient information when Revital-Ox Resert High Level Disinfectant had been used. *Test for the concentration of the Revital-Ox Resert High Level Disinfectant between each vaginal probe cleaning. *Ensure multiple surgical instruments that had been wrapped with surgical tape were free from cracks, rips, tears, and discoloration. *Ensure multiple surgical instruments had surgical tape wrapped 1.5 times around the | C1140 | Probe Cleaning: Staff sonographers will be educated on the disinfection policy for probes, importance of accurate documentation of chemical name used, proof of review of the IFU's for the Trophon and Resert, and the instruction provided by surgical staff on proper procedure and steps to use when using Resert. Competencies will be performed annually with staff on proper procedure for probe cleaning. The Resert disinfection process will be moved to the Surgery Department. Probes will be transported in appropriate biohazard container and disinfected according to the manufacturer's IFU by the sonography staff. Logs for the Resert and Trophon have been updated to include all missing information identified during the survey. Test strips for the Resert have been ordered and will be available for future Resert usage needs. The Radiology Manager is responsible for monitoring and reporting compliance of the changes and process of the probe disinfection process. Monitoring will be reported at the quarterly quality committee meetings for six months. Reports from the quality committee are given to the Board of Directors at the next Board Meeting following the committee meeting. The deficiency will be resolved as of 12-29-25. | 12/29/25 |

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| C1140 | <p>Continued From page 4 instrument, applied flat, and without gaps per the manufacturer's IFU.</p> <p>Findings include:</p> <p>1. Observation and interview on 12/3/25 at 9:14 a.m. of the ultrasound room with sonographer F and sonographer G revealed:</p> <ul style="list-style-type: none"> *Three endocavity vaginal probes were stored in the room. *A Trophon Sonex-HL (automated system to disinfect ultrasound probes) was located on the counter. *They stated the Trophon was used to disinfect the probes. *They have had to use a different disinfectant when the Trophon was not working. *They stated they believed Cidex (a brand name for a disinfectant) was the disinfectant that was used but would check with supply chain manager H. *When the vaginal probes were disinfected in the Trophon, they would have documented patient information on a log. *They would document Cidex used and the dates used when the Trophon was not working. <p>Review of the provider's Trophon 2 High Level Disinfection (HLD) log revealed:</p> <ul style="list-style-type: none"> *There was documentation that Cidex (a brand of disinfectant) had been used to clean vaginal probes from 6/1/25 to 9/1/25. *There was no documentation Revital-Ox had been used by the provider. *The was no documentation for the amount of time the probe was in the Revital-Ox. *The temperature of the Revital-Ox was not documented. *There was no documentation of test strips being | C1140 | <p>Surgical Instrument Taping: The OR team will continue to use specialized identification tape for labeling of all surgical instruments. The policy has been updated for clarification. Staff will follow policy and IFU procedure process. Staff will be educated on policy updates and IFU process and will be signed off on the education on or before 1-2-26.</p> <p>All instruments, including those identified during survey, have been pulled and re-taped with new color coded surgical tape. We have gone through the ED, Clinic, and OB Departments since the survey, pulled every instrument that was taped, removed all the tape, and either re-taped or deleted the tape completely. Education was provided to ED, Clinic and OB staff regarding the tape on the instruments. They will report any tape that is loose or frayed and remove from circulation. OR/CSR staff will assess every instrument that comes back to CSR, re-tape if necessary, and document these actions taken. The CSR staff will be observing ER, OB, and Clinic Departments each month when outdating to audit all instruments. Improvement monitoring activities will consist of the assessment for fraying, discoloration, cracks or tears, gaps, and that the tape is wrapped 1.5 times around the handle of the instrument. They will also monitor the number of instruments that the tape was replaced on. The instruments will be re-taped if needed and then actions will be documented.</p> | 1/2/26 |

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| C1140 | <p>Continued From page 5</p> <p>used to test the minimum effective concentration of the HLD.</p> <p>*There was no documentation of how often Revital-Ox solution was used.</p> <p>*There had not been a log to document patient information, vaginal probe that was used, and if HLD parameters had been met.</p> <p>*She thought director of quality and IC B had trained them on using Revital-Ox but was not sure when.</p> <p>Review of the undated Revital-Ox Resert High Level Disinfectant IFU label revealed:</p> <p>*The probe should have been in the solution for eight minutes and the soak time should have been tracked with a timer.</p> <p>*Minimum temperature of the solution should have been 68 degrees Fahrenheit (F).</p> <p>*Tests strips should have been used prior to each disinfection to test if the minimum recommended concentration was met.</p> <p>*The solution should have been discarded after 21 days.</p> <p>Interview on 12/3/25 at 9:40 a.m. with supply chain manager H revealed the provider had been using Revital-Ox Resert HLD prior to June of 2025.</p> <p>Interview on 12/3/25 at 10:35 a.m. with sonographer F revealed:</p> <p>*She confirmed they had used Revital-Ox instead of Cidex when the Trophon was down.</p> <p>*Documentation of the Cidex being used was incorrect.</p> <p>*They had not created a separate log for the Revital-Ox HLD.</p> <p>*She was not aware of the manufacturer's IFU's.</p> <p>*She was not aware they should have used test</p> | C1140 | <p>Tape outdates will be part of the routine outdate supply checks. Any outdated will be reported from the surgery team to the Supply Chain Manager. The supply chain manager does track all outdated supplies and reports to CFO quarterly. Quality Improvement will be completed on every instrument prior to washing and disinfecting for one year. Instruments will be checked for proper wrapping per IFU, rips, tears, cracks, discoloration, gaps, and chips. Tape will be replaced immediately if any noted defects are found in the tape. The OR Manager will be responsible for monitoring and reporting quality improvement monitoring activities to the Quality Committee on a quarterly basis for one year. Reports from the quality committee are given to the Board of Directors at the next Board Meeting following the committee meeting.</p> <p>The deficiency will be resolved as of 1-2-26.</p> | | |

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| C1140 | <p>Continued From page 6</p> <p>strips prior to the disinfection process to ensure the solution was at the required concentration level.</p> <p>*She was not aware they need to use a log to document the submersion time and solution temperature.</p> <p>*She thought the director of quality and infection control (IC) B had trained them.</p> <p>Interview on 12/4/25 at 10:32 a.m. with director of quality and IC B revealed:</p> <p>*The sonographers were not doing the HLD procedure correctly when the Trophon was not working.</p> <p>*Test strips should have been used.</p> <p>*She was not aware of the process that was used for disinfection when the Trophon was not working.</p> <p>*She had not trained sonographers F and G to use the Revital-Ox.</p> <p>*She agreed the process for disinfection used by sonographers F and G when the Trophon was down was not correct.</p> <p>Review of the provider's 11/2025 Ultrasound Probe Disinfection policy revealed:</p> <p>*If the Nanosonics Trophon is down, use Revital-Ox Resert for disinfectant.</p> <p>**"Follow instructions for use from Revital-Ox for proper steps for disinfection."</p> <p>2. Observation on 12/2/25 at 3:40 p.m. in the labor and delivery unit revealed:</p> <p>*Two peel packs (disposable packages used to hold instruments during sterilization) containing a sterile scissor and a pair of tweezers that were ready for patient use, contained surgical tape.</p> <p>*The surgical tape had:</p> | C1140 | | |

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| C1140 | <p>Continued From page 7</p> <ul style="list-style-type: none"> -Been placed flat on the instrument. -Not been wrapped 1.5 times around the instrument per the manufacturer's IFU. -Not been laid flat without gaps. -Had cracks, tears, and discoloration. <p>Observation on 12/2/25 at 4:00 p.m. in the emergency department revealed: *A single ring forceps (instrument used for grasping, holding firmly, or exerting traction upon objects) contained within a sterilized surgical pack and ready for patient use had surgical tape which had been: -Wrapped more than 1.5 times around the handle of the instrument. -Not been laid flat without gaps.</p> <p>Interview on 12/2/25 at 4:15 p.m. with operating room supervisor C and surgical technician (ST) E regarding the above instruments revealed: *Surgical instruments containing tape are inspected before sterilization to ensure the tape was correctly placed on the instrument. *If the tape needs to be replaced, that was done in the sterile processing department. *She agreed that those tape issues created the potential for bacteria to remain on surgical instruments that could potentially infect the patient leading to serious complications. *She agreed that the tape should have been removed and replaced per the manufacturer's IFU.</p> <p>Observation on 12/3/25 at 9:45 a.m. in the sterile processing room revealed: *Two peel packs containing sterilized scissors. *The surgical instruments contained tape that: -Had been wrapped more than 1.5 times around the handle of the instrument.</p> | C1140 | | | |

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| C1140 | <p>Continued From page 8</p> <p>-Was not laid flat without gaps.</p> <p>Observation on 12/3/25 at 9:30 a.m. in the clinic procedure rooms revealed:</p> <ul style="list-style-type: none"> *Four peel packs containing sterilized scissors and one peel pack containing a sterilized forceps. *The surgical instruments contained tape that: <ul style="list-style-type: none"> -Had been wrapped more than 1.5 times around the handle of the instrument. -Was not laid flat without gaps. -Had cracks. <p>Interview on 12/3/25 at 9:45 a.m. with clinic manager L revealed:</p> <ul style="list-style-type: none"> * Instruments used in the clinic are taped to distinguish them from hospital instruments. *Tape on instruments should have been inspected by the hospital's sterile processing staff. *They did not have a clinic policy regarding the taping of surgical instruments. *She would have expected the surgical staff to follow the manufacturer's IFU regarding surgical tape. *She agreed that issues with surgical tape created the potential for bacteria to remain on surgical instruments that could potentially infect the patient leading to serious complications. <p>Interview on 12/3/25 at 10:00 a.m. with ST D revealed:</p> <ul style="list-style-type: none"> *Instruments that needed sterilization and contained surgical tape should have been inspected to ensure the tape was placed correctly and undamaged. *She stated, "I'm sorry, I must have missed those instruments you had found yesterday. I will get them retaped, but I did not realize the tape had an expiration date, so I will need to order more tape." | C1140 | | |
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| C1140 | <p>Continued From page 9</p> <p>*All instruments used in the clinic are taped to ensure they are returned to the clinic after sterilization. They would not have taped instruments used in the operating room.</p> <p>*She would have followed the manufacturer's IFU to reapply surgical tape to instruments.</p> <p>Interview on 12/3/25 at 12:15 p.m. with the director of acute patient A confirmed: *The provider did not have a policy specifically on the use and care of tape on surgical instruments. *Staff would have been expected to inspect each instrument containing tape, replace as needed, and follow the manufacturer's IFU.</p> <p>Interview on 12/4/25 at 9:13 a.m. with the director of quality, infection control B revealed: *She would have expected staff to inspect the surgical tape on instruments and replace it as needed per the manufacturer's IFU. *She agreed that issues with surgical tape created the potential for bacteria to remain on surgical instruments.</p> <p>Review of the provider's 4/2025 Decontamination of Instruments policy revealed, "All surgical instrument and medical device or equipment manufacturer's validated instructions should be followed regarding the types of cleaning methods to be used for decontamination.</p> <p>Review of the provider's 3/2023 Instrument Cleaning and Processing policy revealed, "All instruments, equipment and supplies to be used for patient care and procedures must be appropriately processed according to the manufacturers written instructions for use to ensure they are free from infectious bacteria."</p> | C1140 | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 431300 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 12/04/2025 |
|---|---|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER MADISON REGIONAL HEALTH SYSTEM | | | STREET ADDRESS, CITY, STATE, ZIP CODE 323 SW 10TH ST MADISON, SD 57042 | | |
| (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 | |
| C1140 | Continued From page 10 Review of the manufacturer's revised 6/2018 Key Surgical Identification Tape IFU revealed: *Wrap tape 1.5 times on a stainless-steel instrument. Tape should lay flat without gaps. *Inspect tape prior to each use. Identification tape is not intended as a permanent mark and will discolor, break, chip, or flake over time. *Replace as soon as these are noticed." | C1140 | | | |

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

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| NAME OF PROVIDER OR SUPPLIER MADISON REGIONAL HEALTH SYSTEM | STREET ADDRESS, CITY, STATE, ZIP CODE 323 SW 10TH ST MADISON, SD 57042 |
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| E 000 | Initial Comments | E 000 | Memorandum of Understanding for Emergency Fuel Delivery was received and signed by fuel vendor on 12-4-25 and the Memorandum of Understanding for Emergency Potable Water was received and signed by water vendor on 12-18-25. The Memorandum of Understandings for fuel and potable water delivery will be updated annually. The Administrative Support Manager will add these to the contract management software system to ensure MOU's are signed on an ongoing annual basis. | 12/18/2025 |
| E 004 | Develop EP Plan, Review and Update Annually CFR(s): 485.625(a) §403.748(a), §416.54(a), §418.113(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §483.475(a), §484.102(a), §485.68(a), §485.542(a), §485.625(a), §485.727(a), §485.920(a), §486.360(a), §491.12(a), §494.62(a). The [facility] must comply with all applicable Federal, State and local emergency preparedness requirements. The [facility] must develop establish and maintain a comprehensive emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements: (a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be [reviewed], and updated at least every 2 years. The plan must do all of the following: * [For hospitals at §482.15 and CAHs at §485.625(a):] Emergency Plan. The [hospital or CAH] must comply with all applicable Federal, State, and local emergency preparedness requirements. The [hospital or CAH] must | E 004 | | |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Teresa Mallett | TITLE CEO | (X6) DATE 12/29/2025 |
|--|-------------------------|------------------------------------|

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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| NAME OF PROVIDER OR SUPPLIER MADISON REGIONAL HEALTH SYSTEM | | STREET ADDRESS, CITY, STATE, ZIP CODE 323 SW 10TH ST MADISON, SD 57042 | | |
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| E 004 | <p>Continued From page 1</p> <p>develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach.</p> <p>* [For LTC Facilities at §483.73(a):] Emergency Plan. The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually.</p> <p>* [For ESRD Facilities at §494.62(a):] Emergency Plan. The ESRD facility must develop and maintain an emergency preparedness plan that must be [evaluated], and updated at least every 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the provider failed to update the emergency preparedness plan agreements (emergency fuel delivery) annually.</p> <p>Findings include:</p> <p>1. Record review on 12/3/25 at 3:38 p.m. revealed no documentation that the provider's current emergency preparedness plan memorandums of understanding/agreements were updated annually. For example, the emergency fuel delivery had not been updated annually since 2020.</p> <p>Interview with the Director of Quality, Safety, and Emergency Preparedness at that same time confirmed that finding. She stated they did not have a more current agreement.</p> | E 004 | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 431300 | (X2) MULTIPLE CONSTRUCTION A. BUILDING 03 - BUILDING 03 B. WING _____ | (X3) DATE SURVEY COMPLETED 12/03/2025 |
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| NAME OF PROVIDER OR SUPPLIER MADISON REGIONAL HEALTH SYSTEM | STREET ADDRESS, CITY, STATE, ZIP CODE 323 SW 10TH ST MADISON, SD 57042 |
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| K 000 | INITIAL COMMENTS A recertification survey was conducted on 12/3/25 for compliance with 42 CFR 485.623 (d) (1) requirements for Critical Access Hospitals (and swing beds) Madison Regional Health System was found not in compliance . The building will meet the requirements of the 2012 LSC for existing health care occupancies upon correction of the deficiencies identified at K132 and K923 in conjunction with the provider's commitment to continued compliance with the fire safety standards. | K 000 | | |
| K 132 | Multiple Occupancies - Contiguous Non-Health CFR(s): NFPA 101 Multiple Occupancies - Contiguous Non-Health Care Occupancies Non-health care occupancies that are located immediately next to a Health Care Occupancy, but are primarily intended to provide outpatient services are permitted to be classified as Business or Ambulatory Health Care Occupancies, provided the facilities are separated by construction having not less than 2-hour fire resistance-rated construction, and are not intended to provide services simultaneously for four or more inpatients. Outpatient surgical departments must be classified as Ambulatory Health Care Occupancy regardless of the number of patients served. 18.1.3.4.1, 19.1.3.4.1 This STANDARD is not met as evidenced by: Based on observation, testing, and interview, the provider failed to maintain the fire-resistive rating for one of one randomly observed two-hour building separation wall (at the door to Avera home medical equipment). | K 132 | Vendor for fire and safety inspections was on-site on 12-16-2025 to fix the door and verified the door between tenant space and hospital did fully function to close automatically and latch when the fire alarm was activated. The Director of Environmental Services is responsible for the ongoing monitoring of this door to ensure proper closing. Monitoring will take place with each monthly fire alarm drill conducted. The Director of Environmental Services will do the monitoring. Compliance will be reported on a quarterly basis to the Safety Committee and the Quality Committee for a period of at least six months. Reports from these committees are given to the Board of Directors at the next Board Meeting following the committee meetings. The deficiency is resolved as of 12-16-25. | 12/16/2025 |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Teresa Mallett <i>Teresa Mallett</i> | TITLE CEO | (X6) DATE 12/26/2025 |
|---|------------------|-----------------------------|

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.

12/29/2025

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| NAME OF PROVIDER OR SUPPLIER MADISON REGIONAL HEALTH SYSTEM | | | STREET ADDRESS, CITY, STATE, ZIP CODE 323 SW 10TH ST MADISON, SD 57042 | |
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| K 132 | Continued From page 1 Findings include: 1. Observation and testing on 12/3/25 at 3:02 p.m. revealed the ninety-minute door in the two-hour, fire-rated separation wall between the hospital and the Avera home medical equipment suite did not automatically close and latch when the fire alarm was activated for a fire drill. That door leaf must automatically close and latch to maintain the two-hour fire-rating of the wall assembly between the business and healthcare occupancies. Interview with the maintenance director at the time of the observation confirmed that finding. He stated he was unaware that condition existed. The deficiency could affect 100% of the occupants of the smoke compartments on either side of the fire-barrier. | K 132 | | |
| K 923 | Gas Equipment - Cylinder and Container Storage CFR(s): NFPA 101 Gas Equipment - Cylinder and Container Storage Greater than or equal to 3,000 cubic feet Storage locations are designed, constructed, and ventilated in accordance with 5.1.3.3.2 and 5.1.3.3.3. >300 but <3,000 cubic feet Storage locations are outdoors in an enclosure or within an enclosed interior space of non- or limited- combustible construction, with door (or gates outdoors) that can be secured. Oxidizing gases are not stored with flammables, and are separated from combustibles by 20 feet (5 feet if sprinklered) or enclosed in a cabinet of | K 923 | The combustible materials stored adjacent to and within five feet of the oxygen cylinders in the gas equipment storage room were removed as of 12-19-25. Only gas equipment will be stored in this room going forward. The Director of Quality, Safety, & Emergency Preparedness will monitor to ensure compliance on a monthly basis. Compliance will be reported at the quarterly Safety Committee meeting. Report from the Safety committee is given to the Board of Directors at the next Board Meeting following the committee meeting. The deficiency is resolved as of 12-19-25. | 12/19/2025 |

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| K 923 | <p>Continued From page 2</p> <p>noncombustible construction having a minimum 1/2 hr. fire protection rating. Less than or equal to 300 cubic feet In a single smoke compartment, individual cylinders available for immediate use in patient care areas with an aggregate volume of less than or equal to 300 cubic feet are not required to be stored in an enclosure. Cylinders must be handled with precautions as specified in 11.6.2. A precautionary sign readable from 5 feet is on each door or gate of a cylinder storage room, where the sign includes the wording as a minimum "CAUTION: OXIDIZING GAS(ES) STORED WITHIN NO SMOKING." Storage is planned so cylinders are used in order of which they are received from the supplier. Empty cylinders are segregated from full cylinders. When facility employs cylinders with integral pressure gauge, a threshold pressure considered empty is established. Empty cylinders are marked to avoid confusion. Cylinders stored in the open are protected from weather. 11.3.1, 11.3.2, 11.3.3, 11.3.4, 11.6.5 (NFPA 99) This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to maintain medical gas storage as required. Combustible items were stored within five feet of the oxygen cylinders in one of one observed central storage oxygen storage room.</p> <p>Findings include:</p> <p>1. Observation on 12/3/25 at 12:21 p.m. revealed combustible materials were stored adjacent to and within five feet of oxygen cylinders in the lower-level med room. Sixteen E-sized oxygen cylinders were found stored in an oxygen cylinder rack. Those cylinders were stored approximately three feet from several cases of supplies (N95</p> | K 923 | | |

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| K 923 | Continued From page 3 masks and Gowns). Interview with the maintenance director at that same time confirmed that finding. He stated he was unaware those oxygen cylinders were stored in that manner in that location. The deficiency had the potential to affect all occupants of the smoke compartment. | K 923 | | | |

South Dakota Department of Health

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 49870S | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 12/04/2025 |
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| NAME OF PROVIDER OR SUPPLIER MADISON REGIONAL HEALTH SYSTEM | STREET ADDRESS, CITY, STATE, ZIP CODE 323 SW 10TH ST MADISON, SD 57042 |
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|--------------------|--|---------------|---|--------------------|
| S 000 | <p>Compliance/Noncompliance Statement</p> <p>A licensure survey for compliance with the Administrative Rules of South Dakota, Article 44:75, Hospitals, Specialized Hospital, and Critical Access Hospital facilities, was conducted from 12/02/2025 through 12/04/2025. Madison Regional Health System was found in compliance.</p> | S 000 | | |

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

Teresa Mallett

Teresa Mallett

TITLE

CEO

(X6) DATE

12/26/2025