Partnership News & Best Practices

Office of Health Facilities Licensure & Certification

SD Department of Health | August 2024, Partnership News

A: 600 E Capitol Ave. Pierre, SD 57501 | P: 605.773.3356

CONTENTS:

Surveyor Electronic Health Record (EHR) Access

Cassie Deffenbaugh, Administrator

The Office of Licensure and Certification (OLC) would like to remind providers that per S&C-09-53, 42 CFR 489.53, and applicable provider state operations manual appendices, surveyors should have unrestricted access to the medical record.

Based on federal regulations, impeding the survey process by unnecessarily delaying or restricting access to the medical records may lead to citation and is grounds for termination from Medicare participation.

Please review your provider-specific regulations surrounding surveyor medical record access to ensure your facility complies with federal regulations.

Elopements in an Assisted Living Center (ALC)

Jennifer Maeschen, Assistant Administrator

Residents with exit seeking behaviors or residents who have a potential for elopement can be a high-risk situation for a provider. To ensure the health and safety of residents within an ALC, residents who are at risk for elopement should be evaluated and assessed routinely. The assessment should include the resident's behaviors related to exit seeking, history of wandering or elopement(s), their mobility, cognition, decision making, and safety awareness. The facility should have policies addressing resident safety and potential/actual elopement or missing persons to ensure staff have guidance to follow. As with other areas in healthcare, it is best practice to ensure and document the actions and communication of the interdisciplinary team, the resident/representative, and the practitioner as they relate to residents with exit seeking behaviors and/or history of elopement(s).

SOUTH DAKOTA DEPARTMENT OF HEALTH
Every South Dakotan Healthy and Strong

While elopement is not specifically mentioned in the administrative rules for ALCs, the expectation would be for the provider to have policies regarding resident safety. Typically, if our office found a concern in this area, it relates to an identified safety risk, no assessments of the resident's abilities and safety related to exit seeking behaviors or elopements, no policies or policies in place but not being followed, or lack of or ineffective staff training related to the residents' needs.

This area would be reviewed through observation and interviews with staff and residents during the survey. If there are concerns identified, surveyors would continue investigating with record reviews and policy reviews.

Here are some questions surveyors may review while in the building:

- Are the facility doors in compliance with our rules for locking, alarming, or monitoring?
- What kind of door system(s) does the facility have and are they functioning as they should?
- Are staff knowledgeable of the doors, alarms, systems?
- If an alarm sounds are staff responding appropriately, ignoring it, or just resetting it without checking why it was sounding?
- Are residents' assessments, care plans, and interventions in place and appropriate to their needs if they have cognitive impairment or are at risk for elopement?
- Are staff trained and aware of the facility's processes for door alarms, cognitive impairment, missing residents or elopements, abuse and neglect, reporting, emergency response/ preparedness, etc.?

Concerns with resident elopements would potentially be cited under one or more of the following administrative rules:

44:70:01:05. Acceptance and retention of residents which states "*A facility may only accept and retain residents based on the facility's capabilities to meet the needs of the residents. The facility may accept or retain residents in accordance with the services provided by the facility, determined by the governing body, and with written policies and procedures…"*

44:70:01:07. Reports to the department which states *"Each facility shall report the following events to the department through the department's online reporting system within twenty-four hours of the discovery of the event:…*

(2) Any cause to suspect abuse or neglect of a resident;…
(4) A missing resident;…

The facility shall conduct an internal investigation for the event and report the results to the department no later than five working days after the event.

The department may request additional information from the facility and investigate any reported event."

44:70:02:17 Occupant protection which states *"…must be constructed, arranged, equipped, maintained, and operated to avoid injury or danger to any occupant…*

(5) Install an electrically activated audible alarm, if required by other sections of this article, on any unattended exit door. Any other exterior door must be locked or alarmed. The alarm must be audible at a designated staff station and may not automatically silence if the door is closed…"

44:70:04:04. Personnel training which states "*The facility shall have a formal orientation program and an ongoing education program for all healthcare personnel. Ongoing education programs must cover the required subjects annually. These programs must be completed within thirty days of hire for all healthcare personnel and must include the following subjects:…*

(4) Accident prevention and safety procedures;…
(7) Incidents and diseases subject to mandatory reporting and the facility's reporting mechanisms;…
(11) Any additional healthcare personnel education necessary based on the individualized resident care needs provided by the healthcare personnel to the residents who are accepted and retained in the facility."

44:70:04:06. Admissions or retention of residents which states *"…facility may admit and retain, on the orders of a physician, physician assistant, or nurse practitioner, only those residents for whom it can provide care safely and effectively."*

44:70:04:11 Care policies which states *"…shall establish and maintain policies, procedures, and practices that follow accepted standards of professional practice to govern care, and related medical or other services necessary to meet the residents' needs…"*

44:70:05:01 Nursing policies and procedures which states *"…shall establish and maintain policies and procedures that provide the nursing staff with methods of meeting the facility's administrative and technical responsibilities in providing care to residents. The policies shall include the following…(7) Resident safety;…"*

44:70:05:02. Resident care plans, service plans, and programs which states "*The facility shall provide safe and effective care from the day of admission through the development and implementation of a written care plan or service plan for each resident. The care plan or service plan must address personal care, and the medical, physical, mental, and emotional needs of the resident…"*

44:70:05:07. Care of a resident with cognitive impairment which states *"Each facility shall use a validated screening tool for evaluation of a resident's cognitive status upon admission, yearly, and after a significant change in condition.*

A facility that admits or retains a resident with cognitive impairment shall have the resident's physician, physician assistant, or nurse practitioner determine and document if services offered by the facility continue to enhance the resident's functioning in activities of daily living. The physician, physician assistant, or nurse practitioner shall identify if other disabilities and illnesses are impacting the resident's cognitive and mental functioning. The facility shall be equipped with exit alarms installed in compliance with subdivision 44:70:02:17(5).

The facility shall have policies and procedures based on the facility's capabilities to meet the needs of the residents."

If your facility has residents who exhibit exit seeking behaviors or residents that are at risk for elopement, we encourage you to look at your policies, assessment processes, documentation, and staff training. Ultimately, the goal is to ensure safe and effective care to all residents while also following the requirements of the administrative rules. We hope this information is helpful to anyone navigating this area in an ALC setting. For questions, please contact Shelly Walstead at 605-367-4640 or shelly.walstead@state.sd.us.

Understanding the Spaulding Classification and Why It's Important

Heidi M. Durband, MSN, RN, HACP-CMS, CPAN
Acute Care Advisor

The Spaulding Classification system is used to determine what type of disinfection or sterilization is appropriate for reusable medical devices. This classification system divides medical devices into categories based on the risk of infection involved with their use and it is widely accepted and used by the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and medical health professionals. The three medical device categories are broken down into non-critical, semi-critical, and critical.

1. **Non-critical:** Devices that do not ordinarily touch the patient or come in contact with intact skin. Devices such as blood pressure cuffs, stethoscopes, EKG cables, glucometer meters, and mouth guards are classified as non-critical devices. Also included would be a variety of equipment and environmental surfaces that become contaminated during use. The devices can be cleaned using low-level disinfection or manual cleaning processes.

2. **Semi-critical**: Devices that come in contact with intact mucous membranes and do not ordinarily penetrate sterile tissue. These devices should be sterilized, but if sterilization is unavailable, high-level disinfection (HLD) is an acceptable form of disinfection. Devices such as endoscopes, bronchoscopes, probes, respiratory therapy equipment, and laryngoscope blades are classified as non-critical devices.

3. **Critical:** Devices that enter sterile tissue or the vascular system. These devices must be sterilized, which is defined as the destruction of all microbial life. Devices such as surgical instruments, implants, and cardiac and urinary catheters.

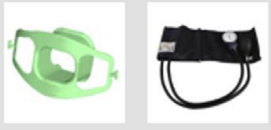
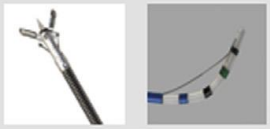
Patient Contact	Device Classification	Examples	Reprocessing
Intact skin	**Non-critical**		Low-level disinfection; Intermediate-level disinfection
Mucous membranes; Non-intact skin	**Semi-critical**		High-level disinfection
Sterile areas of the body; Vascular system	**Critical**		Sterilization

Figure 1. Spaulding classification system for medical devices.
https://www.giejournal.org/cms/attachment/6556faaa-9b08-4f6c-96eb-8ef4b86e1d11/gr1.jpg

Reprocessing modalities are recommended at each level of disinfection in the Spaulding Classification. For non-critical devices, low-level disinfection kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria tuberculosis). Examples would be alcohol, bleach, and quat. Intermediate-level disinfection kills vegetive microorganisms including mycobacterium tuberculosis, all fungi, but does not kill bacterial spores. Some non-critical and semi-critical devices may undergo this disinfection process. High-level disinfection eliminates all microorganisms in or on a device, except for small numbers of bacterial spores. At a minimum, all semi-critical devices should undergo HLD. Examples of HLD include Rapicide PA, glutaraldehyde, hydrogen peroxide, peracetic acid, and Cidex OPA.

Sterilization is the complete elimination of all viable microbial life, including spores from a medical device. It can be achieved through two methods: physical and chemical. Physical sterilization includes heat, radiation, and filtration. Chemical sterilization includes alcohols, oxidizing agents, and ethylene oxide gas. It is important to note that meticulous cleaning must come first prior to HLD and sterilization process and to follow the devices manufacturer's instructions for use (MIFU). Proper use and disinfection of medical devices is imperative in preventing infection and providing patients with safe, quality care. Understanding and using the Spaulding Classification along with manufacturer's IFU will guide health care professionals to ensure each medical device is properly cleaned, disinfected, and sterilized and ready for patient use.

Achieving Quality Waived Testing

Denise Broadbent
CLIA Advisor

The number of waived test methods is growing exponentially and with it comes the potential for issues with the quality of the reported results. Waived tests are defined as simple to perform and with a low risk for erroneous results, but this does not mean that waived tests are completely error-proof.

Some waived tests have potential for serious health impacts if performed incorrectly. For example, results from waived tests can be used to adjust medication dosages, such as prothrombin time testing in patients undergoing anticoagulant therapy and glucose monitoring in diabetic patients. In addition, erroneous results from diagnostic tests, such as those for human immunodeficiency virus (HIV) and syphilis antibodies, can have unintended consequences.

To decrease the risk of erroneous results, the test needs to be performed correctly, by trained personnel and in an environment where good laboratory practices are followed. Quality waived testing begins well before the test is performed.

Below are some best practices and considerations:

- Testing personnel must have appropriate training and need to have their competency assessed in each test they will be performing prior to beginning patient testing. It is the responsibility of the laboratory director or other supervisory staff to ensure this training has occurred and is documented. Periodic competency evaluation is recommended to ensure staff are performing waived testing correctly and accurately. Retraining may be needed if staff are not performing the test method correctly.

- Development of a manual with written procedures and policies. The procedures should be developed with the assistance of the manufacturer's instructions for use. They should include the appropriate specimen type/source as necessary, sample collection and handling, test/reagent preparation, instructions on performing the test correctly, and interpretation and documentation of test results. The procedure should also include how to perform quality control testing, including frequency of testing, documentation of results, and what to do in the case of unacceptable quality control results. Many smaller point of care analyzers also have required maintenance which will need to be documented.

- Confirm the written test order is correct. If in doubt, check with the ordering provider to confirm the test order.

- Do you have all the necessary supplies to perform the test? Have the quality control materials been tested? Were the results documented? Were the results acceptable? If quality control results are unacceptable – STOP. Determine the cause of the issue and correct it. Retest your quality control material(s). Do not perform patient testing if the quality control results are unacceptable.

- Use two unique identifiers to ensure accurate identification of your patient before you collect the specimen. Use the patient's name and their birth date or medical record number. If the test requires any special preparation, for example the patient needs to be fasting, verify this before collecting the specimen. Ensure all specimens are correctly labeled immediately after collection.

- Follow the steps in the test procedure exactly as documented in the manufacturer's instructions for use. Failure to perform the test correctly could result in inaccurate test results.

- Interpret the results in accordance with the manufacturer's instructions. Document the results in the patient's medical record. Ensure the results were entered accurately. Do the results require confirmatory testing? If so, follow the referring laboratory's instructions for specimen collection and handling. Ensure the confirmatory testing results are received and documented in the patient's chart.

Achieving quality waived testing is possible. If you have any questions related to waived testing, please contact the CLIA office at SDCLIA@state.sd.us.

Is It Elopement?

Diana Weiland, RN
LTC Advisor

The front door alarm sounded, staff responded, and found Mary on the sidewalk just feet from the door. The plan worked…

Staff were notified by a passerby someone was lying face down on the sidewalk just outside the facility. Responding staff discovered John had exited the facility unnoticed.

In the middle of the night when the door alarm sounded, staff responded, checked the door, finding nothing amiss, turned off the alarm and did not identify Henry was missing.

When a resident leaves the facility, was it a planned event or an elopement?

Elopement occurs when an identified resident leaves the premises or a safe area unnoticed without authorization and/or necessary supervision to do so. Simply stated, elopement occurs when an individual "breaches" the door or "walks or moves over the threshold." An elopement can happen without any noticeable signs of their cognitive impairment. All three of the above situations was an elopement. Regulations indicate the provider must conduct an initial and periodic comprehensive, accurate, standardized reproducible assessment of each resident's functional capacity. The regulations hold the provider accountable for the resident's care and safety. Assessment is the ultimate tool in the toolbox. Recently, there have been events that occurred where it appeared assessment, assessment of risks, or lack of identification of risks transpired, creating potential for resident harm or causing resident harm and injury.

Considerations and observations when evaluating for elopement risk:

- Resident is ambulatory or self-mobile in wheelchair
- Resident is a new admission who has made statements questioning the need to be there
- Resident has cognitive impairment with poor decision-making skills and/or pertinent diagnosis
- Resident is alert but non-complaint with the protocols regarding leaving the facility
- Resident has a history of wandering (either in the facility or elsewhere)
- Resident is opening doors to the outside and/or elopement
- Resident is making statements that they are leaving or seeking to find someone/something
- Resident displays behaviors, body language, or other signs/symptoms indicating an elopement may be forthcoming

When assessing elopement risk and interventions, it is necessary for care plans to include both similar and differing strategies for those with cognitive impairment in comparison to those who are cognitively intact. Not all who elope have cognitive impairment.

Secure doors and windows and wander management systems do not replace the necessary and adequate supervision of the resident(s). No matter how secure your facility is, the best way to assure residents are not eloping is to have staff present and conducting regular rounds.

Those times when the monitoring plan may need to be adjusted to prevent elopements includes, but is not limited to: new admission periods, night shift, shift change, mealtime, fire drills/alarms, during the holidays, or if the facility has higher traffic or people in and out such as renovation projects or changing out equipment.

Facility policies should clearly define the mechanisms and procedures for assessing or identifying, monitoring, and managing residents at risk for elopement. The resident at risk should have interventions in their comprehensive care plan to address the potential for elopement. Additionally, the provider's disaster and emergency preparedness plan should include a plan to locate a missing resident.

Office of Licensure and Certification Staff Contact
https://doh.sd.gov/providers/licensure/StaffContacts.aspx

Name	Title	Email	Phone
Cassie Deffenbaugh, RN	**Administrator**	Cassandra.Deffenbaugh@state.sd.us	605-773-3356
Jennifer Maeschen, RN	**Assistant Administrator**	Jennifer.Maeschen@state.sd.us	605-995-8147
Carrie Christopherson, RN	**Western Regional Manager:** Hospice, Home Health, and PRTF Advisor	Carrie.Christopherson@state.sd.us	605-773-3694
Jean Koch, RN	**Eastern Regional Manager**	Jean.Koch@state.sd.us	605-995-8985
Heidi Durband, RN	Acute Care Advisor	Heidi.Durband@state.sd.us	605-910-7186
Diana Weiland, RN	Nursing Home Advisor	Diana.Weiland@state.sd.us	605-995-8057
Shelly Walstead, RN	ALC, RLC, CLH, and AFC Advisor	Shelly.Walstead@state.sd.us	605-367-7499 or 605-367-4640
Jim Bailey	Medical Facilities Engineering Supervisor	James.Bailey@state.sd.us	605-367-5434
Julie Jenssen	Licensing, Certification and Enforcement	Julie.Jenssen@state.sd.us	605-773-3901
Jolene Juneau, RN	Complaint and CNA Advisor	Jolene.Juneau@state.sd.us	605-773-6373
Denise Broadbent MT (ASCP)	Laboratory Advisor	Denise.Broadbent@state.sd.us	605-394-6173
John Priest	Radiology & Rural Health Clinic Advisor	John.Priest@state.sd.us	605-367-5672
Tina Muller, LNHA	MDS Coordinator	Tina.Muller@state.sd.us	605-773-5116
Rachel Landmark MS, RD, LN	Surveyor Education Coordinator	Rachel.Landmark@state.sd.us	605-367-5441

SOUTH DAKOTA DEPARTMENT OF HEALTH
Every South Dakotan Healthy and Strong