Partnership News & Best Practices

Office of Health Facilities Licensure & Certification

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Welcome to New Office of Licensure & Certification Leadership

Cassie Deffenbaugh, RN, Administrator

The Office of Licensure and Certification (OLC) recently bid farewell to two longtime staff serving as Assistant Administrators. Patricia Brinkley and Deb Carlson have retired from the Department of Health, each with over 20 years of dedicated service to OLC. Their commitment to protecting the health and safety of South Dakota's patients and residents will have an everlasting impact. As a result of Patricia and Deb's retirements, OLC has welcomed several new staff into a new organizational structure and leadership positions:

- Jennifer Maeschen, previous RN Advisor for Assisted Living Centers, Adult Foster Care, Community Living Homes, and Residential Living Homes, is our new Assistant Administrator and will provide oversight to our Advisors, Quality Assurance Coordinator, and Training Coordinator.
- Jean Koch, previous RN Advisor for Acute and Continuing Care (ACC) providers, is our Eastern Regional Manager overseeing our team of surveyors based out of our Sioux Falls office.
- Carrie Christopherson, previous RN Health Facilities Surveyor, is our Western Regional Manager, overseeing our team of surveyors in Mitchell, Pierre, Rapid City, and Spearfish. Carrie is also the new advisor for Home Health, Hospice, and Psychiatric Residential Treatment Facilities (PRTF).
- Shelly Walstead, previous RN Advisor for Complaints and CNA enforcement, is now the Advisor for Assisted Living Centers, Adult Foster Care, Community Living Homes, and Residential Living Homes.
- Jolene Juneau, previous RN Health Facilities Surveyor supporting the Complaints Department, is now the RN Complaint and CNA Enforcement Advisor.
- Heidi Durband, RN, will join OLC as the ACC Advisor in April!

We are excited about these opportunities and are committed to continuing to protect and promote the health of South Dakota's patients and residents.

Medical Facility License Renewals

Julie Jenssen

The annual medical facility license renewal period is just around the corner.

Administrators, please be on the lookout for an email to renew your annual medical facility license. Renewal notifications will be sent to the email address of the Administrator we have on record on **May 15, 2024**. If you do not receive an email, please check your junk email folder prior to contacting our office. The renewal emails will be sent from the following email address: DOHOLCLicensing@state.sd.us.

Providers will need the following information in order to access their online renewal:

1. Administrators email address *(please note if you are a new administrator at a facility, you won't be the administrator email on file until our office has been notified and we have received a letter from your governing board*)
2. Facility license number
3. Name of facility

The renewals need to be reviewed, updated, and submitted no later than **June 28, 2024**.

Payment for license renewals for most provider types is now collected once your renewal has been reviewed and approved. We are actively working to transition the remainder of the providers to this payment format. Those that have not migrated by May 15, 2024, will continue to pay at the time the renewal is submitted. As a reminder, payments will need to be made via credit card or a non-cash voucher *(please note, the non-cash voucher is only available for South Dakota state facilities).* Also, our system only accepts **Visa** or **Mastercard** credit cards.

We look forward to working with you on your upcoming license renewal. Please don't hesitate to contact our staff at 605.773.3356 or via email at DOHOLCLicensing@state.sd.us.

Registration of Residential Living Centers

Jennifer Maeschen, RN, Assistant Administrator

South Dakota Codified Laws (SDCL) require residential living centers to register annually with our office. These centers are not licensed healthcare facilities; they are considered registered. While the Department of Health (DOH) references them as residential living centers we recognize they may also be known as independent living, retirement living, elderly apartments, etc. For further information please review the following information.

SDCL 34-12-32 states:

> *Any person engaged in the business of operating a home or facility for the purpose of providing residential services for compensation to two or more elderly or disabled persons not related to the owner by blood or marriage shall register annually with the State Department of Health, unless otherwise required to be licensed under this chapter. As used in this section, the term, "residential services," means room, meals, and daily living services, but not habilitative or health care. The department shall establish procedures and provide forms for registration. No fee may be established for registration. To implement this section, the State Department of Health may adopt rules pursuant to chapter 1-26. Failure to register pursuant to this section is a Class 2 misdemeanor.*

SDCL 34-12 addresses licensing and registration. SDCL 34-12-32, SDCL 34-12-33, and SDCL 34-12-34 specifically relate to residential living centers. Article 44:23 of the administrative rules also relates to residential living centers.

DOH does not regularly survey these centers. However, an onsite DOH investigation in relation to a concern or complaint could occur according to SDCL 34-12-33 referenced above.

Each year around December an annual registration renewal reminder is sent to each residential living center in our records. The center submits an online renewal application that is then reviewed and approved by our office, like the annual renewals for licensed healthcare facilities that occurs in June each year. There is no fee for initial applications or renewal applications of residential living centers.

If your licensed facility has residential/independent living units attached to, within, or associated with your campus, please ensure you are registered with our office.

If your residential living center has not been registered with DOH previously, we request completion of the online **Residential Living Center Registration Application** located on our DOH application page for the initial application.

> Note – On the online residential living application, the capacity section should only include the residential living center's capacity, units, and residents currently residing there. The license for the other areas of your campus (i.e., nursing facility, assisted living, or hospital) would already have those units licensed and accounted for separately.

If you have any questions on residential living centers, you may reach out to our main office or contact Shelly Walstead.

The Virtual Patient Monitoring System

Jean Koch, RN, Eastern Regional Manager

Healthcare providers have been faced with several challenges related to nursing shortages, increased patient complexities, and increased patient fall rates. As a result of these challenges, among several others, healthcare systems have had to get creative and consider new ways for delivering care to reduce the burden on bedside staff.

In many medical circumstances, clinicians and caregivers may choose not to leave a patient alone. For example, a patient may present a fall risk, experience confusion and agitation, or be at-risk for self-harm. In such situations, a hospital may assign a 1:1 sitter, or a caregiver who provides patient supervision.

A virtual patient monitoring system is a continuous visual two-way monitoring system that uses advanced audio and video technology to monitor multiple patients simultaneously from a single remote location. These systems can be referenced as "telesitters" that can track patient activity and notify staff of concerns or emergency situations that may be occurring. This system allows monitoring of several patients at once, freeing up patient care technicians and nurses to focus on clinical duties.

Most virtual patient monitoring systems consist of portable camera units mounted on rolling IV-like poles and provides live video and auditory feeds from the patient's room. They operate as a closed-circuit camera network where a clinical technician can monitor video feeds of 12 – 57 patients at a time. Should the technician notice something astray in a patient room, the technician can broadcast a message either to the patient or sound an alarm to notify staff.

The virtual patient monitoring system is an example of innovative progress for the patient care experience. However, the shift from an in-person 1:1 sitter to the two-way video monitoring system does introduce a concern with the patients' care environment and their right to privacy. When utilizing the use of a video monitoring system, there is potential for violation of privacy during personal care, private phone conversations, private visitation, or other issues related to privacy. Video monitoring should not be used in instances when there is risk of privacy to be violated.

Protecting the patient's rights to privacy is of great importance to the Centers for Medicare and Medicaid Services (CMS) and the Department of Health (DOH). It is recommended that the following key factors be considered when using a virtual patient monitoring system:

- Provide education to the patient or their advocate that continuous video monitoring could be implemented to promote patient safety and what continuous virtual monitoring would consist of.
- Obtain a written informed consent from every affected client or designated guardian prior to the implementation and use of the virtual monitoring system.
- Develop policies specific to the use of a virtual monitoring system that supports the process and how patient rights, and privacy will be maintained.
    - The policy should address (not all inclusive):
        - How all hospital and family caregivers involved with the use of the virtual monitoring system will provide patient privacy and confidentiality.
        - When privacy mode is needed and when patient view can be re-instated.
        - The written informed consent process.
        - Documentation requirements to support the use of the virtual monitoring system for the physicians, professional staff, technicians, and caregivers.
- Provide education for the caregivers and technicians related to documentation requirements while use of the virtual monitoring system.
- Provide initial and ongoing staff education to avoid non-compliance with policy.
- Determine and outline requirements for physician involvement and orders.
- Determine and outline assessment requirements for the patient prior to the use of a virtual monitoring system.
- Determine and outline individualized plan of care requirements.

CLIA Electronic Certificates

Connor McVay, MLT (ASCP)

Effective September 26, 2023, all CLIA laboratories that had previously received either a paper or electronic certificate are now able to print their own copy from the quality certification and oversight reports (QCOR) clinical laboratory lookup tool. The link displayed with your laboratory will be the most recently issued CLIA certificate. New changes will be updated in the next issued certificate.

On November 22, 2023, CMS began sending electronic fee coupon notices to laboratories that checked the box to receive email notifications on their applications (Form CMS-116). Like electronic certificates, laboratories will receive an email with a link to their fee coupon, which they can use to print a copy if they choose not to pay online. The box to check to receive email notifications is on page one of the application.

Do you want to update an email address or opt to get email notifications?

- In order to update your email address or opt in to email notifications, a laboratory must give written notification to the appropriate State Agency (SDCLIA@state.sd.us, Connor.Mcvay@state.sd.us, or Denise.Broadbent@state.sd.us). Federal jurisdiction laboratories should contact their CMS Location.

Sexual Expression and Intimacy in Long-Term Care

Diana Weiland, RN, LTC Advisor

Just because an individual is older or in a nursing home doesn't mean they will not have a need to express themselves sexually. An individual's age, health problems, or disabilities does not stop a person from expressing themselves. Sexual expression may benefit an individual physically, mentally, and emotionally.

Acts of sexual expression – self-expression, affection, and sexual gratification include but are not all inclusive:

- Physical sex acts with a partner
- Sexting
- Flirting
- Masturbation
- Holding hands
- Hugging
- Kissing
- Cuddling in bed

Long-Term Care facilities are "homes" for the persons living in them; they are workplaces for the staff. Those residing in them are entitled to privacy, respect, and should be able to have self-expression in their homes. To that end, an individual's sexual expression should not infringe on or upset the safety and comfort of others living there and care staff. Clear communication about where and when they may enjoy their privacy need to be established.

Those with capacity to consent maintain the right to:

- Consensual sexual relations
- Privacy
- Choice – to say No, to end a relationship
- Freedom from abuse

For the individual(s) living with dementia, assessment and active collaboration with their spokesperson(s) and the care provider team can assist in reviewing and helping the individual(s) maintain comfort and connection. Those lacking capacity to provide consent may still express the desire to receive human touch and be comforted by it through their actions. These individuals maintain the right to be treated with dignity and respect and to not be abused.

Recently, surveyors have investigated situations when there were no polices or plans that addressed resident sexual expression and intimacy. When preparing or reviewing policies and plans, there should be medical director and other physician involvement. Policies and plans should include the individual's ability to make an informed choice to participate in sexual activities.

In South Dakota, by law, a person is incapable of giving informed consent if:

- A guardian has been appointed for the person.
- The court has determined the person to be legally incompetent.
- It has been determined in good faith by the person's attending physician.

South Dakota does <u>not</u> provide a definition for consent, but it provides that no consent exists for an act of sexual penetration accomplished with any persons under the following circumstances:
… (2) Through the use of force, coercion, or threats of immediate and great bodily harm against the victim or other persons within the victim's presence, accompanied by apparent power of execution….

… (3) If the victim is incapable, because of physical or mental incapacity, of giving consent to act….

The definition does not require "freely given consent" or "affirmative consent."
Elderly age does not impact the victim's ability to consent. However, according to South Dakota Codified Law (SDCL) 22-22-7.2, developmental disability and/or mental incapacity does impact the victim's ability to consent.

In addition to establishing an individual's ability to exercise informed consent, the facility policy should address:

- Acknowledgment of South Dakota rules
- Prevention of sexual abuse
- Confirmation of resident's rights to establish and maintain a relationship

Facility staff should receive training and education to:

- Follow and actively support the facility policy about individual sexual expression and intimacy
- Protect individuals' safety, confidentiality, and privacy
- Ensure everyone's right to safety and healthy sexual expression is recognized, respected, maintained, and supported

Bed Rails in an Assisted Living Center (ALC)

Jennifer Maeschen, RN, Assistant Administrator

Bed rails or side rails can be a high-risk area in any setting. To ensure the health and safety of residents within an ALC, bed rails or other devices should be assessed routinely. The assessment should include the resident's use/need for them, if they meet safety specifications (such as the Food and Drug Administration (FDA) guidelines), if the manufacturers' instructions for use are followed, etc. There should be policies addressing them and to ensure staff have guidance and direction 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.

While bed rail assessments are not specifically required in the administrative rules for ALCs, the expectation would be that the provider has a policy related to how the facility handles bed rails while ensuring the residents are kept safe in relation to them. Typically, if our office found a concern in this area it would be because there is a safety risk to the resident(s), there were no assessments of the resident's abilities and safety related to the bed rails, there were no policies, or the policy was not being followed.

Bed rail concerns could potentially be cited under the following rules:

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

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…(6) Resident safety;…"*

Bed rails could also be viewed as a potential restraint if they meet the definition under **44:70:01(35**) which states, *"…a physical, chemical, or mechanical device used to restrict the movement of a resident or the movement or normal function of a portion of the resident's body, excluding devices used for specific medical and surgical treatment."*

If your facility has residents who have bed rails or a resident is planning to add them, 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.

CLIA Fee and CoW Updates

Connor McVay, MLT (ASCP)

On December 28, 2023, CMS Directors, Quality, Safety and Oversight Group (QSOG) released QSO-24-03-CLIA. This final rule updates the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fee regulations. It also updates regulations to allow the Centers for Medicare and Medicaid Services (CMS) to impose alternative sanctions on Certificate of Waiver (CoW) laboratories, when appropriate. These changes are effective January 27, 2024.

The CLIA program is funded through user fees paid by certified laboratories. In 2018, CMS issued the first fee increase in 20 years. This 20 percent increase was a temporary solution to help fund the program while CMS worked on the changes below.

CMS CLIA user fees will increase as follows:

1) Establishing fees that are currently authorized fees that were not previously assessed. The following are program services that will result in fees:
    a. Performing follow up surveys to determine correction of deficient practices observed in either Certificate of Compliance (CoC) or Certificate of Accreditation (CoA) surveys.
    b. Adding a fee when it is necessary to determine compliance of testing in one or more additional specialties outside of the CoC survey cycle.
    c. Performing a substantiated complaint survey.
    d. Performing desk review of unsuccessful proficiency testing (PT) performance to ensure successful proficiency testing by laboratories.
    e. Issuing a revised or replacement certificate ($75-$150 depending upon the certificate type).
2) Imposing an 18 percent across-the-board increase to existing fees.
3) Increasing the certificate fee for Cow laboratories by $25.
4) Increasing fees every two years based on a two-part calculation of the Consumer Price Index-Urban (CPI-U) inflation adjustment, and, if applicable, an additional across the board increase.

Alternative Sanctions for CoW Laboratories, 493.1804(c)(1) is also updated in this final rule. CoW laboratories are labs that only perform waived testing, which is testing has a low risk of an incorrect result. Some examples of waived testing include dipstick urinalysis, urine pregnancy tests, and fecal occult blood testing. The regulations used to state that we do not impose alternative sanctions on CoW laboratories because those labs are not inspected on a regular basis. However, CoW laboratories can be surveyed as a result of a complaint. Based on a complaint survey, a lab can be found out of compliance for a condition level requirement. The ability to impose sanctions on CoW laboratories helps CMS ensure they are in compliance, as is the case for the other certificate types. Alternative sanctions can include, civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring.

If you have questions please contact Denise Broadbent (Denise.Broadbent@state.sd.us) or Connor McVay (Connor.Mcvay@state.sd.us).

The 14-hour Rule and "Nourishing Snacks"

Rachel K. Landmark, MS, RD, LN

During survey, surveyors assess long-term care facilities dietetic services. One of the first things we ask for is the times meals are served. We do this to determine if more than 14 hours are between the evening meal and breakfast the next day. What should you do if more than 14 hours are between meals? You have a couple of options.

First and foremost, have a discussion with the resident council. If they are agreeable to moving the mealtimes, then change the meal schedule to accommodate the 14-hour rule. If they do not mind that more than 14 hours are between meals, then you must offer a "nourishing snack" at bedtime.

F809 in Appendix PP covers the requirement for the frequency of meals:
"§483.60(f)(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except when a nourishing snack is served at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span." A nourishing snack is defined as "items from the basic food groups, either singly or in combination with each other," according to Appendix PP.

Secondly, ask your residents what they would like to see on the snack menu and work with your registered dietitian to develop that menu. Review your facility's diet manual – it might have suggestions for nourishing snacks! (LTC facilities are required to have a diet manual under ARSD 44:73:07:12).

Here are some examples:

- Sandwiches: Peanut butter and jelly, egg salad, deli meat and cheese
- Crackers and a protein: cheese, nut butters, cottage cheese, deli meats, meat salads
- Fruit and a protein: fresh or canned fruit, nut butters, yogurt, cottage cheese, cheese sticks
- Cereal and milk
- Granola bar
- Milk and a cookie
- And many more!

Once you have a menu written, develop a policy to outline expectations. Your policy should address the timeframe of when the bedtime snack should be served, who will be preparing the snacks, who will be serving the snacks, and what to do if a resident doesn't want the snack. Before implementing your bedtime snack rotation, educate staff about the policy and expectations and document who received that education. Remember to have fun with creating your menus and get the residents involved!

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https://doh.sd.gov/providers/licensure/StaffContacts.aspx

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