We hope you will benefit from the information contained within this newsletter. The Partnership News will be sent via email several times during the year. Please contact Chris Qualm if you have any questions or special requests for information you would like to see in the newsletter. My email address is chris.qualm@state.sd.us

Welcome to the first edition of the Office of Health Care Licensure and Certification newsletter, Partnership News & Best Practice. The goals of this newsletter are to improve communication and to share information with our partners.

Through these partnerships, we feel we can best meet the needs of those we serve. As noted in our mission statement, we want to partner with you to ensure the health, safety, and appropriate care of patients and residents in South Dakota.

We know the health care provider community in South Dakota provides some of the best health care in the nation.

Goal of this Newsletter

Change of Administrator or DON

The Office of Health Care Facilities Licensure & Certification would like to take this opportunity to remind our health care partners to notify our office when a change in administrator occurs. According to the Administrative Rules of South Dakota 44:04:04:03 for Medical Facilities and 44:70:04:02 for Assisted Living Centers, the “governing body” shall notify the department in writing of any change of administrator. We request this notification be sent prior to the departure of the current administrator to ensure we have adequate time to update our records appropriately. Since the Centers for Medicare and Medicaid Services (CMS) is now communicating strictly via email with providers, we would also like to request the administrator’s email address be included in the letter. Acceptable forms of communication for this change are:

- mail a written request to Chris Qualm, Administrator, South Dakota Department of Health, 615 E 4th Street, Pierre, SD 57501;
- fax a written request to Chris Qualm, Administrator, South Dakota Department of Health, 605-773-6667;
- or send an email to chris.qualm@state.sd.us

Although there is no administrative rule governing the notification of changes in the Director of Nursing position, we request the administrator to please notify our office of these changes as well. Please feel free to contact our office at 605-773-3356 if you have any questions.
Hospice News

CMS announced November 14, 2014 the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT). The Act mandates Medicare certified hospices are surveyed no less than every 36 months starting six months after the enactment of the Act. All of the certified hospice providers are required to be surveyed from April 6, 2015 through April 6, 2018. In SD there are 14 certified hospice providers. Two of the hospice providers have deemed status that are surveyed by an accreditation organization. SD Department of Health developed a plan to survey four certified hospice providers each year to ensure compliance with the IMPACT Act of 2014. Previously hospice providers were surveyed at an interval of 6.5 to 7 years.

SD DOH reassured CMS Denver Regional Office the department would be able to complete one-third of the hospice surveys yearly by April 6, 2018. The department has three trained and qualified surveyors to complete the hospice surveys. The surveyors are Connie Stenzel, a social worker and two registered nurses, Kathy Roby and Deb Wegleitner.

Hospice deficiencies cited:

L629 Supervision of the hospice aide - When the EMR was set up no automatic reminder had been set up to remind the registered nurse to complete the supervisory visit.

L652 Services – Medications were not delivered in a timely manner, a request for a volunteer was not provided, and no replacement for the hospice aide when the aide was not available.

L652 Services – Medications were not delivered in a timely manner, a request for a volunteer was not provided, and no replacement for the hospice aide when the aide was not available.

L702 Use and Maintenance of equipment and supplies - There was no documentation in the EMR the risk factors had been identified or for any education provided to the patient regarding safety. During the home visit it was observed the patient had oxygen cylinders at the end of the bed. There was an ashtray with cigarette butts next to the bed and the sheet on the window had cigarette burn holes present.

L710 Inpatient care for Respite Care - Observation revealed the patient who was not able to make her needs known cried out in pain during bathing. The documentation revealed during bathing, repositioning, or during any care the patient cried out in pain. The assessment had determined it was not associated to pain however, it was unclear how that determination had been made.

L733 Infection Control – Observation revealed while wearing gloves perineal care and catheter care was provided. Without removing those gloves the staff person then washed the patient’s arms, legs, and then the patients face.

Please contact Deb Wegleitner, RN at 605-995-8073 or email at Deb.Wegleitner@state.sd.us if you have questions.

Life Safety Code

One item which has been cited by Federal Life Safety code surveyors is the failure to provide a remote stop bottom for the emergency generator. This is a requirement for nursing homes and hospitals. A remote stop button similar to a break glass station is to be provided outside the room where your generator is located and this is also required for generators mounted outdoors. We have asked the CMS Regional Office and they say the remote stop button for the outdoor generator may be located on the outside of the generator housing.
Rules Package

The proposed Department of Health rules have been posted on the SD.GOV at https://rules.sd.gov/default.aspx and DOH http://doh.sd.gov/news/ websites. The public hearing is scheduled for August 26, 2015, at 1:00 p.m. to 5:00 p.m. at the Mathew’s Training Center in Pierre. Modifications have been made to the original draft rules based on comments and further review. The rules being submitted are as follows:

- 44:04 Medical Facilities
- 44:73 Nursing Facilities
- 44:74 Nurse Aides
- 44:75 Hospital, Specialized Hospitals, and Critical Access Hospital Facilities
- 44:76 Ambulatory Surgery Center Facilities
- 44:77 Adult Foster Care Facilities
- 44:78 Inpatient Chemical Dependency Treatment Facilities
- 44:79 Inpatient Hospice Facilities
- 44:80 Residential Hospice Facilities
- 44:03 Radiation Safety
- 44:72 Redistribution of Nursing Facility Beds

If you have any questions please feel free to contact Chris Qualm at chris.qualm@state.sd.us.

Recall Notices

Below you will find useful links for recall notices from the Food and Drug Administration (FDA) and Consumer Products Safety Commission (CPSC).

We would encourage you to sign-up for the notices that pertain to your facility sent via email by the organizations. The notices will be sent to you and will include food and drug recalls to equipment and manufacturer recalls. As always, please let us know should you have any questions or concerns.

https://public.govdelivery.com/accounts/USFDA/subscriber/new?preferences=true

Over the last several years most skilled nursing facilities have begun to promote they are “restraint free”. However they continue to use side rails, citing the use allows the individual to maintain independence in their bed mobility, transferring, and repositioning; individual and family choice; or it offers a “sense of security.”

It is not enough to have an individual or family request the use. A physician’s order is not enough to implement the use of a side rail. Many factors need to be considered before making the decision to use side rails.

The process for consideration for use of side rails starts with assessment. Assessment includes:

- Individual identified medical need with reassessment on a regular basis and with any change in condition. Assessment reveals side rail as a restrictive/restraint device or one that is enabling.

- Individual cognition or comprehension for the safe use of the side rail. There is greater potential for injury when a fall occurs from a bed with elevated side rails when the individual attempts to climb over, around, or between the rails, than from a bed with no side rails. Determine risk of injury.

- Review the bed system. The bed system encompasses the bed frame and its components, including the mattress, side rails, head and foot board, and any accessories added to the bed.

- Manufacturer’s recommendations for use of the bed system should be followed.

- “Entrapment” describes an event in which an individual is caught, trapped, or entangled in the space in or about the bed rail, mattress, or bed frame.

- All side rails, including those used to assist mobility, transferring, and repositioning do require a physician order and should be addressed on the individual’s care plan. The documentation should reflect education of the individual or responsible individual spokesperson regarding the risks versus the benefits of side rail use. The least restrictive device necessary to meet the individual’s needs should be used.

- When side rails serve no medical purpose, the Hospital Bed Safety Workgroup (HBSW) recommends they should be avoided. When side rails keep individuals from voluntarily getting out of bed, they are deemed physical restraints.

An immediate reassessment for use and safety should occur if there is a fall from the bed or if an episode of entrapment or near entrapment occurs, with or without injury.

The HBSW and the Food and Drug Administration (FDA) have defined seven numbered “zones” or spaces in and around bed systems where individuals could potentially become trapped. Actual entrapments have been reported in six of these zones, with Zones 1, 2, 3, and 4 accounting for approximately 80% of entrapment events reported to the FDA.

Reference: US Food and Drug Administration Website. Copy this link to your internet browser to open:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072662.htm

Please contact Diana Weiland at 605-995-8057 or email Diana.Weiland@state.sd.us if you have questions.
**Zone 1: Within the Rail.**
Zone 1 is any open space within the perimeter of the rail. Openings in the rail should be small enough to prevent the head from entering. A loosened bar or rail can change the size of the space. The recommended space should be less than 120 mm (4 3/4 inches), representing head breadth.

**Zone 2: Under the Rail, Between the Rail Supports or Next to a Single Rail Support.** Preventing the head from entering under the rail would most likely avoid neck entrapment in this space. FDA recommends this space be small enough to prevent head entrapment, less than 120 mm (4 3/4 inches).

**Zone 3: Between the Rail and the Mattress.** FDA is recommending a dimensional limit of less than 120 mm (4 3/4 inches) for the area between the inside surface of the rail and the compressed mattress.

**Zone 4: Under the Rail, at the Ends of the Rail.** FDA recommends the dimensional limit for this space also be less than 60 mm (2 3/8 inches).

**Zone 5: Between Split Bed Rails.** This zone occurs when partial length head and foot side rails (split rails) are used on the same side of the bed. The space between the split rails may present a risk of either neck entrapment or chest entrapment between the rails if a patient attempts to, or accidentally, exits the bed at this location.

**Zone 6: Between the End of the Rail and the Side Edge of the Head or Foot Board.** This space may present a risk of either neck entrapment or chest entrapment.

**Zone 7: Between the Head or Foot Board and the Mattress End.** This space may present a risk of head entrapment when taking into account the mattress compressibility, any shift of the mattress, and degree of play from loosened head or foot boards.

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**Active Shooter Policies**

We have become aware that many facilities have been developing Active Shooter policies. Please keep in mind that an exit door which becomes locked to prevent someone from leaving the building is in violation of the Life Safety Code. Any modification you make to your building should be approved by our department to make sure you will be in compliance with the rules.
The mission of the South Dakota Department of Health, Office of Health Care Facilities Licensure and Certification is to partner with consumers, families, healthcare providers, healthcare organizations, and other regulatory agencies to ensure the health, safety, and appropriate care of patients and residents in South Dakota.