Office of Health Care Facilities Licensure and Certification,
South Dakota Department of Health

Partnership News

& Best Practice

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Greetings from OLC!

Inside this issue:

My job affords me the privilege and opportunity to visit with staff from facilities across South Dakota as well as through the associations. During the course of the conversations, many times the discussion leads to the quality care the patients and residents receive while in facilities.

Although we are a regulatory agency, we feel it better serves the patients and residents to work in a collaborative manner with the health care providers.

Our dedicated surveyor staff willingly travel across the state each and every week inspecting facilities, working with your staff and acting as another set of eyes for the care of the patients and residents. I frequently hear from OLC staff of the many great things facility staff do on a daily basis.

We understand surveys seem stressful for some but we feel they ultimately lead to quality of care for the beneficiaries. Deficiencies may be written and technical assistance may be provided.

The survey process should be one of mutual respect and professionalism. Quality of care is achieved by working together.

I welcome calls or emails from Administrators with comments and suggestions.

My phone is 605.773.3356 and email address is chris.qualm@state.sd.us

Thank you.

Chris

FDA Requires Boxed Warnings and Patient-Focused Medication Guides

Special points of interest:

- ***Nursing Home Compare:*** *http://www.medicare.gov/nursinghomecompare/?AspxAutoDetectCookieSupport=1*
- ***CMS S&C's:*** *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html*

The Food and Drug Administration (FDA) is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines.

Specifically, after an extensive review of the latest scientific evidence, the FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

The FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management.

The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD

New Long Term Care Regulations

Event reporting Link:

http://doh.sd.gov/providers/licensure/complaints.aspx

The Reporting of injuries of unknown and reasonable suspicion of a crime algorithm is located at the following link:

http://doh.sd.gov/documents/Providers/Licensure/Reporting_Final.pdf

CMS has issued updated rules within the requirements for long-term care facilities to reflect current practice standards of person-centered care, improving resident safety and quality of life. This is the first comprehensive review since 1991.

The rules were updated due to the substantial changes in the service and delivery of care in long term care. At the same time, there have been significant innovations in resident care and quality assessment practices.

Highlighted updates are seen in quality assurance and performance improvement (QAPI) program, the infection prevention and control program (IPCP), and a compliance and ethics program at all Medicare-certified skilled nursing facilities and Medicaid-certified nursing facilities. Changes in this rule will be phased in over three years.

The first phase of implementation will occur upon the effective date of the final rule (November 28, 2016) and include those requirements that were unchanged or received minor modification. Training will be provided to surveyors and providers.

The second phase of implementation will have a deadline of 1 year following the effective date of the final rule and in addition to those requirements implemented in phase one, this phase will also include those brand new requirements and provisions that required more complex revisions. The additional time for implementation will allow for complete changes in our survey processes as well as updates to the survey guidance. CMS will provide updated guidance to facilities, update the traditional and QIS survey process, update the survey tags in accordance with the reorganization of the regulations, and provide training to surveyors on the new tags.

The third and final phase of implementation will have a deadline of 3 years from the effective date of the final rule and include all the remaining requirements that were not implemented in phases 1 and 2. This final phase will allow for the complete set of revised requirements to be incorporated into the practices of LTC facilities and sufficiently enforced through the updated survey process.

The final rule can be accessed at the following link:

https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities

Training for Phase 1 Implementation of New LTC Regulations.

The CMS Training for Phase 1 Implementation of New Nursing Home Regulations outlines regulatory changes to occur in phase I.

The training is open and available to all providers. Any providers who wish to access the training it is located at http://surveyortraining.cms.hhs.gov/pubs/ProviderTraining.aspx and will be available until July 2017.

The online training does not take long (approximately 1 - 1 1/2 hours).

OLC Complaint Program—Online Reporting System

The OLC Complaint Program thanks all of you for the smooth transition to the updated online reporting system. After working with the system we have noted the following:

•When it is time to complete the **final** reporting, log onto the Launchpad application, click complaint forms on the left hand side of the screen. Then about one-half way down the page there is a status button, click on it to activate all the check marks. There you should now see the list of reports you have submitted, pick the **initial** report that you want to document the final investigation on. Click on the edit button, once the report is open click final and then scroll down the report and place your conclusion/final investigation in the appropriate area. This will update that report and show the paper trail within one report. You are then able to print that report for your records.

•Please do not send these reports to the Ombudsman program, they do not require these reports.
•The Department of Social Services only needs to be contacted if you have not notified the law enforcement or States Attorney with an abuse, neglect, or exploitation of older adults or persons with disabilities. This is your mandatory reporting requirement. As for the DOH, we would **expect** law enforcement or the States Attorney to be notified of these crimes.

Please contact LaJeanne Armstrong at 605-773.3356 if you have questions.

New Emergency Preparedness Regulations

On September 8, 2016 the Federal Register posted the final rule Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers. Health care providers and suppliers affected by this rule must comply and implement all regulations one year after the effective date, on November 16, 2017.

By the November 16, 2017, deadline providers affected must:

⇒ Conduct a **risk assessment and emergency planning** that utilizes an all-hazard approach to emergency preparedness planning.

⇒ Establish **policies and procedures** that support successful execution of the emergency plan and risks identified with the risk assessment.

⇒ Develop and maintain a **communication plan** for contacting staff, patients, physicians, and other necessary individuals in a timely manner.

⇒ Conduct **training and testing** of the emergency preparedness plan. Training is required initially for new and existing staff and annually thereafter. Healthcare facilities affected will be required to conduct drills and exercises which can identify gaps or areas needing improvement.

The purpose of the new regulations is to establish national emergency preparedness requirements to ensure adequate planning for both natural and man-made disasters, and coordination with federal, state, tribal, regional and local emergency preparedness systems. The following information will apply upon publication of the final rule:

- Requirements will apply to all 17 provider and supplier types.
- Each provider and supplier will have its own set of Emergency Preparedness regulations incorporated into its set of conditions or requirements for certification.
- Must be in compliance with Emergency Preparedness regulations to participate in the Medicare or Medicaid program.

Numerous resources exist to support the regulation, including guidance for surveyors:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html

The South Dakota Hospital Preparedness Program works with hospitals and other medical facilities to ensure that South Dakota's medical community is as prepared as we can be!

Visit the website at http://doh.sd.gov/providers/Preparedness/Hospital-Preparedness/

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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.

http://doh.sd.gov/providers/licensure/

SOUTH DAKOTA DEPARTMENT OF HEALTH

Emergency Eyewash Stations are Paramount to Safety

The American National Standards Institute (ANSI) has a standard, American National Standard for Emergency Eyewash and Shower Equipment. This document "establishes minimum performance and use requirements for eyewash and shower equipment" for anyone whose eyes or body have been exposed to hazardous materials or chemicals.

There are two types of emergency eyewashes; plumbed units (connected to a water source) and self-contained (has its own supply of water). The self-contained type must deliver a minimum of 1.5 liters per minute (0.4 gallons per minute (gpm) over a 15-minute period while the plumbed type must deliver 11.4 liters per minute (3.0 gpm) over the same period of time. The design should permit hands-free operation and flush both eyes at the same time. The water temperature should be in the range of 60 to 100 degrees F. to avoid any potential damage to ocular tissue. The bottle-type eyewash units are not acceptable because they do not meet the criteria as established by ANSI.

- Additional requirements include:
  The location of the eyewash should be identified with a highly visible sign and the area should be well-lit.
- Employees should be trained in the location, use and testing of emergency eyewash stations per the manufacturer's written instructions.
- Eyewashes should be tested at least weekly for efficacy. The unit should be turned on and allowed to run for 15 minutes or as directed by the manufacturer.
- While testing the unit, verify the water temperature using a thermometer.
- Ensure the protective caps are on the unit; if missing they must be replaced.
- Document the testing on a log form, including the water temperature.
- The self-contained units should be visually checked weekly to ensure there is sufficient water volume or if the solution needs to be changed.
- Installation of the eyewash should be in compliance with the manufacturer as well as ANSIZ358.1, 2014.

Safety in the workplace is paramount. It is the responsibility of the facility to purchase and install the required equipment.

References:
The American National Standard for Emergency Eyewash and Shower Equipment, Z358.1-2014.

FDA issues final rule on safety and effectiveness of antibacterial soaps

The U.S. Food and Drug Administration today issued a final rule establishing over-the-counter (OTC) consumer antiseptic wash products containing certain active ingredients can no longer be marketed. Companies will no longer be able to market antibacterial washes with these ingredients because manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections. Some manufacturers have already started removing these ingredients from their products. This final rule applies to consumer antiseptic wash products containing one or more of 19 specific active ingredients, including the most commonly used ingredients – triclosan and triclocarban. These products are intended for use with water, and are rinsed off after use. This rule does not affect consumer hand "sanitizers" or wipes, or antibacterial products used in health care settings.

Read more at: **http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm517478.htm?platform=hootsuite**