Indiana State Department of Health

LONG TERM CARE NEWSLETTER

ISDH Long Term Care
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In Today's Issue:

Wound Care Symposium

Wound Care Specialists of Indiana announced the 2013 Indiana Advanced Wound Care Symposium. The Symposium will be October 10 and 11. The Symposium Brochure is attached. The program has been expanded this year to continue basic wound care training while providing more advanced training for experienced providers.

From 2007-2010, Indiana nursing home pressure ulcer rates declined from about 8.5% to 7.0%. While fewer deficiences have been identified and fewer harm and higher level deficiencies, surveyors are still finding a number of deficiencies. The table below indicates the number of pressure ulcer deficiencies cited at Indiana nursing homes.

	Total	Actual Harm	Immediate Jeopardy	
2007	87	41	9	
2008	176	71	4	
2009	155	55	4	
2010	133	45	2	
2011	133	29	3	
2012	125	19	0	
2013	45	8	0	(July 1)

Source: CMS Casper Data 7/8/13; Calendar year all surveys

Pressure ulcers are still a challenge and problem in Indiana health care facilities. The ISDH encourages continued efforts towards decreasing the number of pressure ulcers in health care facilities.

CMS Updates

S&C 13-55-LSC: Sprinklers

The Centers for Medicare and Medicaid Services (CMS) issued a survey and certification letter,S&C 13-55-LSC , on the Installation of Automatic Sprinkler Systems in Nursing Homes. Under federal certification regulations, all nursing homes must be fully sprinklered as of August 13, 2013 in order to participate in Medicare or Medicaid. The sprinkler requirement was published on August 13, 2008 in a final rule entitled *Medicare and Medicaid Programs: Fire Safety Requirements for Long Term Care Facilities, Automatic Sprinkler Systems* . The regulation provided a five-year advance timeframe to achieve full sprinkler status by August 13, 2013. While CMS is not requiring any special surveys focused on the sprinkler requirement, a life-safety code (LSC) inspection is part of each facility's recertification survey. As these surveys occur during the year, facilities that are not fully sprinklered on or after August 13, 2013 will be cited for a deficiency.

The ISDH notes that Indiana law required installation of a sprinkler system and smoke detectors by July 1, 2012. Over the past year, the ISDH has inspected nursing homes for compliance with the state licensing statute.

S&C 13-50-NH: Closure of a Facility

The Centers for Medicare and Medicaid Services (CMS) issued a survey and certification letter, S&C 13-50-NH on notification of an impending closure of a facility.

Under sections 1128I(h) and 1819(h)(4) of the Social Security Act (the Act) and regulations at 42 CFR 483.75(r) and (s), individuals serving as the administrator of a SNF, SNF/NF or NF must provide written notification of an impending closure of a facility which also includes the plan for relocation of residents at least 60 days prior to the impending closure; or, if the Secretary terminates the facility's participation in Medicare or Medicaid, not later than the date the Secretary determines appropriate. Notice must be provided to CMS, the state long term care ombudsman, all the residents of the facility, and the legal representatives of such residents or other responsible parties. A final rule was published in the Federal Register on March 19, 2013 and became effective on April 18, 2013 (78 FR 16795).

An advanced copy of the revisions to Appendix PP of the State Operations Manual (SOM) is attached which revises tags F203 and F204 and adds new tags F523 and F524. The final version of this document, when published in the online SOM, may differ slightly from this interim advanced copy.

Recalls and Advisories

Nationwide Voluntary Recall of All Products for Sterile Use from Compounding Pharmacy located in Cedar Park, Texas

August 15, 2013

Summary:

The U.S. Food and Drug Administration (FDA) is alerting health care providers and patients of a voluntary nationwide recall of all products produced and distributed for sterile use by Specialty Compounding, LLC, Cedar Park, Texas. There have been recent reports of bacterial bloodstream

infections potentially related to the company's calcium gluconate infusions. CDC and the FDA are working with Texas state officials to determine the scope of the contamination.

According to the FDA, information provided by the firm stated that the recalled products (i.e., all products produced and distributed for sterile use by Specialty Compounding) were distributed directly to patients nationwide, with the exception of North Carolina, which received no products. The full text of the recall is available on the FDA website at http://www.fda.gov/Safety/Recalls/ucm364643.htm?source=govdelivery. Also according to the FDA, information provided by the firm stated that recalled products were also distributed to hospitals and physician offices in Texas.

Background

The Texas Department of State Health Services has reported bacterial bloodstream infections in 15 patients from two Texas hospitals who received an infusion of calcium gluconate 2 grams in Sodium Chloride 0.9 percent for Injection, supplied by Specialty Compounding. According to Texas state officials, most infections were caused by Rhodococcus equi and are thought to be related to the infusions. Two of the 15 patients have died. CDC does not have information that the deaths are related to recalled product. Also according to Texas state officials, cultures from an intact sample of calcium gluconate compounded by Specialty Compounding show growth of bacteria that are consistent with Rhodococcus species. Isolates are being evaluated by CDC to confirm the identification.

Recommendations

All sterile use products produced and distributed by Specialty Compounding are being recalled, and none of these products should be used by patients or administered to patients. Facilities, health care providers, and patients who have received the products, should immediately discontinue use, quarantine the products, and return the products to Specialty Compounding (See http://www.fda.gov/Safety/Recalls/ucm364643.htm?source=govdelivery).

If patients who received recalled product are experiencing symptoms, especially fever, they should consult a physician. Patients and physicians should report adverse reactions experienced with the use of any Specialty Compounding products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax. Information on reporting adverse reactions can be found at https://www.accessdata.fda.gov/scripts/medwatch/.