Indiana State Department of Health

LONG TERM CARE NEWSLETTER

ISDH Long Term Care
Newsletter Issue 2013-17
August 30, 2013

In Today's Issue:

CMS Updates

SC 13-56-NH: Minimum Data Set 3.0 Discharge Assessments

The Centers for Medicare & Medicaid Services (CMS) released Survey and Certification 13-56-NH. CMS is clarifying steps to take to address Minimum Data Set (MDS) 3.0 discharge assessments that have not been completed and/or submitted as required under 42 CFR §483.20(g) and 42 CFR §483.20(f)(1). The memo is intended to help surveyors understand both (a) what nursing homes should do to address inactive residents remaining on their resident roster due to incomplete and/or unsubmitted discharge assessments and (b) how nursing homes can ensure compliance with discharge assessment requirements. CMS is providing this information in order to promote nursing home completion of discharge assessments for inactive residents by September 30, 2013.

SC 13-57-NH: Escrow and Independent Informal Dispute Resolution (Independent IDR) Process for Nursing Homes - Applicable to All Civil Money Penalties (CMPs)

CMPs imposed pursuant to all standard or complaint surveys that begin on or after October 1, 2013, that initiate an enforcement action in which a CMP is imposed where the highest level of deficiency is less than a "G" level, will be subject to collection and escrow in accordance with 42 C.F.R. §488.431. CMPs based on surveys in which a deficiency is cited for actual harm or immediate jeopardy ("G" or higher) are already subject to escrow.

Previously, CMS phased in the escrow requirement by limiting it to CMPs imposed for actual harm or immediate jeopardy. Effective October 1, 2013 every CMP imposed for a deficiency in a nursing home will be subject to escrow and the nursing home may request an independent informal dispute resolution.

SC 13-58-LSC: 2000 Edition National Fire Protection Association (NFPA) 101® Life Safety Code (LSC) Waivers

The Centers for Medicare & Medicaid Services (CMS) has identified several areas of the 2000 edition

of the LSC and 1999 edition of NFPA 99 that may result in unreasonable hardship on a large number of certified providers/suppliers and for which there are alternative approaches that provide an equal level of protection. This memorandum specifies the provisions that are available for waiver, including the conditions for the alternative approaches.

Individual waiver applications are not required, but providers and suppliers are expected to have written documentation that they have elected to use a waiver and must notify the survey team at the entrance conference for any survey assessing LSC compliance that it has elected the use of a waiver permitted under this guidance and that it meets the applicable waiver requirements. The survey team will review the information and confirm they are meeting the circumstances for the waiver.

Recalls and Advisories

Isoniazid (INH) Shortage Guidelines Rescinded - Tuberculin Shortage Guidelines Remain in Effect

August 14, 2013
ISONIAZID

The INH shortage appears to be resolved and the shortage designation has been removed from the FDAs website. Please return to pre-shortage guidelines when initiating treatment for new TB and LTBI patients. See below for patients currently being treated using the interim shortage guidelines.

LTBI patients currently on six months of daily Isoniazid (INH) treatment due to interim guidelines: Continue INH for full six months. It is at the clinician's discretion if he/she wishes to prescribe an additional three (3) months of INH treatment for a total of 9 months (the pre-shortage accepted optimal duration of INH treatment).

LTBI patients currently on four months of daily Rifampin (RIF) due to interim guidelines:
Continue the RIF for the full four months.

LTBI patients currently on the twelve week once weekly doses of Rifapentine and INH: Continue treatment for full 12 weeks using directly observed therapy for each weekly dose.

Public Health Nurses will need a physician's script to change from 6 months to 9 months of INH treatment if the original treatment script was for 6 months of INH.

New LTBI patients: Recommendations for treatment prior to shortage should be followed. These include 9 months of daily INH or 12 weeks of once weekly Rifapentine and INH (the accepted optimal treatments), as well as the alternative treatments of 4 months of daily RIF or 6 months of daily INH.

TUBERCULIN

Tuberculin shortage continues, interim guidelines remain in effect until further notice. Indiana State Department of Health's TB Program recommends the following measures until the shortage is resolved.

Recommendations for Responding to Tuberculin Shortages

-- If available and appropriate, screen for LTBI with an Interferon Gamma Release Assay (IGRA) (T-SPOT (R) .TB and QuantiFERON (R) Gold in-tube) instead of a tuberculin skin test (TST).
-- Prioritize TSTs if necessary. High priority groups include:
- Contacts to a person with pulmonary or laryngeal TB

- Persons who are immunoccompromised
- Evaluation of persons with symptoms suggestive of TB disease

-- If necessary, defer annual screening of employees, residents, and/or inmates as part of an infection control plan until sufficient tuberculin becomes available.

If you have questions or encounter problems obtaining INH and/or Tuberculin, please notified the Director of TB/Refugee Health at the Indiana State Department of Health, Sarah Burkholder (317) 233-7545 or email her at sburkholder@isdh.in.gov .

Covidien Monoject Prefill Flush Syringes: Recall - Not Subjected To AutoClave Sterilization Process Or Mismatched Syringe Tip Cap, Syringe Label, Filled Volume And Wrapper

August 20, 2013

ISSUE: Covidien announced that it has initiated a voluntary recall of certain lots of Monoject prefill flush syringes. This recall is being conducted due to the risk that a number of the syringes were filled with water but not subjected to the autoclave sterilization process. These products are labeled as either sodium chloride flush or heparin lock flush. Some of these syringes have the mismatched syringe tip cap, syringe label, filled volume and wrapper. However, for the sodium chloride flush syringes with matched tip cap, syringe label, filled volume and wrapper, there are no visual cues for the clinician to identify the problematic products. If non-sterile fluid is administered there is a health risk of life-threatening infection to the blood stream or other areas. Also if the clinician uses the heparin lock flush syringe containing only water on peripheral or venous catheters, the patency of the intravascular device may not be maintained and clotting may occur. This could result in non-functional intravenous access requiring the device to be replaced.

BACKGROUND: Only Monoject prefill flush syringes from the lot numbers listed are affected by this action (see Firm Press Release for list of affected lot numbers). The lot numbers can be found on the shipper case, carton and individual syringes. Customers are required to identify, segregate and return any affected products in their inventory. Customers have been notified of this issue by letter dated August 16, 2013.