Indiana State Department of Health

LONG TERM CARE NEWSLETTER

ISDH Long Term Care
Newsletter Issue 2013-14
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In Today's Issue:

CMS Update

Survey and Certification 13-42-NH: Access and Visitation Rights in Long Term Care Facilities

The Centers for Medicare and Medicaid Services (CMS) released SC 13-42-NH . The guidance is a reminder of current regulations and Guidance to Surveyors (Interpretive Guidelines) at 42 CFR, Part 483.10(j), F172, Access and Visitation Rights. This guidance delineates the rights of long term care residents to receive family and non-family visitors. Facilities must provide 24-hour access to all individuals visiting with the consent of the resident. Certain visitors may be subject to "reasonable restrictions imposed by the facility that protect the security of all the facility's residents, such as denying access to those engaged in disruptive behavior.

Survey and Certification 13-43-NH: Changes to Nursing Home Compare Website

CMS released SC 13-43-NH regarding changes to Nursing Home Compare. Starting in July 2013, the Centers for Medicare & Medicaid Services will direct users of the Nursing Home Compare website to the data.medicare.gov website to download or view nursing home data. The data.medicare.gov site is the main website for regulators, researchers, quality improvement leads, and other individuals who have a need to download nursing home data. This website should provide better access and navigation for users.

Survey and Certification 13-44-NH: Five-Star Quality Rating System Three Year Report

CMS released SC 13-44-01-NH announcing the release of the Five-Star Quality Rating System Three Year Report. The report (SC 13-44-02-NH) provides the results of an analysis that examined trends in the first three years of the Five-Star Quality Rating System. In the report CMS discusses the distribution of the star ratings in each domain (health inspections, staffing, and quality measures). The report will be available under the download section of the web pages at the following link:

http://www.cms.gov/Medicare/Provider-Enrollment-and-

Certification/CertificationandComplianc/FSQRS.html

Recalls and Advisories

Enteric Coated Aspirin 81 mg Tablets by Advance Pharmaceutical Inc.: Recall of One Lot May Contain Acetaminophen 500 mg Tablets

June 19, 2013

ISSUE: Advance Pharmaceutical Inc. announced that this firm is conducting a voluntary nationwide recall to the user level of the over-the-counter drug product, Rugby label Enteric Coated Aspirin Tablets, 81 mg, Lot 13A026. Advance Pharmaceutical Inc. first initiated the recall on June 17, 2013, after receiving a complaint about a bottle labeled as Enteric Coated Aspirin Tablets, 81 mg, actually containing Acetaminophen 500 mg tablets. Consumers may be inadvertently taking Acetaminophen 500 mg instead of Enteric Coated Aspirin 81 mg which may cause severe liver damage to those who take other drugs containing acetaminophen, consumers who take 3 or more alcoholic drinks every day, or those who have liver disease. The labeled directions instructs patients to take 4-8 tablets every 4 hours, but not more than 48 tablets in 24 hours. Consumers who take 48 tablets daily of the defective product may be ingesting up to 24,000 mg of Acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

BACKGROUND: The product is indicated for the temporary relief of minor aches and pains and is packaged in bottles of 120 tablet with NDC 0536-3086-41 and UPC 3 0536-3086-41 9. The affected lot of Enteric Coated Aspirin Tablets is Lot 13A026 with Expiration Date 01-2015. The lot was manufactured and packaged by Advance Pharmaceutical Inc. under the label of Rugby Laboratories. Rugby Laboratories (Major Pharmaceuticals) distributed the product nationwide to wholesalers and retailers. Advance Pharmaceutical Inc. notified Rugby Laboratories of the recall by e-mail and overnight mail, and is arranging for return of all recalled bottles.

RECOMMENDATION: Consumers who have the affected lot should immediately discontinue its use and return it to the pharmacy or store where it was purchased. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. Any adverse reactions experienced with the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program: