Indiana State Department of Health

LONG TERM CARE NEWSLETTER

ISDH Long Term Care
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In Today's Issue:

HHS will reimburse states for care of Haitian earthquake victims

November 19, 2010:

Medical facilities, professionals and other providers who cared for victims of January's devastating earthquake in Haiti will be reimbursed for the cost of that care, U.S. Department of Health and Human Services Secretary Kathleen Sebelius announced today.

After the Jan. 12, 2010, earthquake hit the island nation, the infrastructure crumbled, leaving the medical community challenged to treat the approximately 300,000 injured individuals. The earthquake also led to more than 200,000 deaths. Even with help offered by many countries, injured Haitians and Americans who were in Haiti at the time had to be evacuated to the United States for medical care. Many evacuees were treated in Florida and Georgia.

"State Medicaid programs and other providers responded without hesitation," said Secretary Sebelius. "These medical professionals generously provided life-saving care to earthquake victims, often at great cost to their practices, hospitals and clinics."

Payments to those who provided medical care that would otherwise be uncompensated will come from a special emergency fund included in the Disaster Relief and Summer Jobs Act of 2010.

"Congress and President Obama recognized the enormity of the tragedy and the unprecedented need for help," said Secretary Sebelius, "This fund will allow HHS to reimburse providers for medical services, honoring the nation's commitment to supplying humanitarian aid."

Many services to evacuees were paid for by state Medicaid and Children's Health Insurance Programs (CHIP), straining already tight state budgets. With the new money set aside in the supplemental fund, the federal government will reimburse states for their share of the costs of those two programs.

The Centers for Medicare & Medicaid Services (CMS) will work with states to determine and verify the costs to Medicaid and CHIP of those seeking post-quake care in the United States. State program claims will be eligible for reimbursement if services were provided to victims of the Haiti earthquake who would otherwise be eligible for Medicaid or CHIP.

Payments for care of Haiti earthquake evacuees is available for up to eight months from the date of the individual's arrival in the United States, but no later than Nov. 10, 2010. States that wish to be reimbursed for their share of the Medicaid or CHIP payments must file claims with CMS by March 1,

2011. Providers who have not already filed claims with state Medicaid or CHIP programs must file claims for care related to the earthquake by March 1, 2011.

Providers who have questions about filing claims or about eligibility to file a claim can send their inquiries to Haiticlaims@hhs.gov. State Medicaid offices that have questions about reimbursement for the state costs of Medicaid or CHIP should contact the regional Medicaid office.

ISDH Updates

Telephone Directory

Attached please find an updated telephone directory for the ISDH Division of Long Term Care and Division of Health Care Education and Quality.

Recalls

November 19, 2010: Propoxyphene: Withdrawal - Risk of Cardiac Toxicity
Sold as Darvon, Darvocet, and generics

ISSUE: FDA notified healthcare professionals that Xanodyne Pharmaceuticals has agreed to withdraw propoxyphene, an opioid pain reliever used to treat mild to moderate pain, from the U.S. market at the request of the FDA, due to new data showing that the drug can cause serious toxicity to the heart, even when used at therapeutic doses. FDA concluded that the safety risks of propoxyphene outweigh its benefits for pain relief at recommended doses. FDA requested that the generic manufacturers of propoxyphene-containing products remove their products as well.

BACKGROUND: FDA's recommendation is based on all available data including data from a new study that evaluated the effects that increasing doses of propoxyphene have on the heart (see Data Summary in Drug Safety Communication). The results of the new study showed that when propoxyphene was taken at therapeutic doses, there were significant changes to the electrical activity of the heart: prolonged PR interval, widened QRS complex and prolonged QT interval. These changes can increase the risk for serious abnormal heart rhythms.

RECOMMENDATION: FDA recommends that healthcare professionals stop prescribing and dispensing propoxyphene-containing products to patients, contact patients currently taking propoxyphene-containing products and ask them to discontinue the drug, inform patients of the risks associated with propoxyphene, and discuss alternative pain management strategies. Patients were advised to dispose of unused propoxyphene in household trash by following the recommendations outlined in the Federal Drug Disposal Guidelines.

November 12, 2010: Sigma Spectrum Infusion Pump Model 35700: Class 1 Recall: Risk of Over-Infusion

Issue: FDA notified healthcare professionals of the class 1 recall of the SIGMA Spectrum Infusion Pump Model 35700. These units may fail suddenly, causing inaccurate flow conditions during use, ranging from back flow to over-infusion, including free flow. The pump does not issue an alarm when this occurs. These conditions could result in serious injury or death.

Background: The recalled pump is intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration. The recall was initiated September 15, 2010 and includes serial numbers from 706497 to 724065.

Recommendations: Sigma has instructed healthcare facilities to verify whether the serial numbers for their infusion pumps fall within the range of pumps being recalled and is requiring the return of the recalled devices. Sigma has instructed users to not use the infusion pumps on patient populations, including neonatal patients, where inaccurate flow, ranging from back flow to over-infusion, including free flow, could result in serious adverse health consequences or death.

October 2, 2010: Heparin Sodium (B. Braun): Recall - Trace Contaminant

ISSUE: B. Braun Medical Inc. and FDA notified healthcare professionals of a nationwide recall of certain lots of Heparin Sodium USP Active Pharmaceutical Ingredient (API) sold to B. Braun because testing indicated a trace amount of oversulfated chondroitin sulfate (OSCS) contaminant. These lots were manufactured in 2008 and will be expiring on October 31, 2010 and November 30, 2010.

BACKGROUND: Heparin is a blood thinner used to treat and prevent blood clots.

RECOMMENDATION: Customers who have product from the recalled product lots in their possession should discontinue use immediately. Product lot numbers, expiration dates, and recall instructions are listed in the Press Release.

October 29, 2010: Methotrexate Injection, 50mg/2mL and 250mg/10mL Vials: Recall - Presence of Glass Particulates

ISSUE: Sandoz and FDA notified healthcare professionals of a recall of Methotrexate Injection, 50mg/2mL and 250mg/10mL vials, due to small glass flakes detected in a limited number of vials in four lots. The flakes are the result of delamination of the glass used to manufacture the vials of the two dosage presentations.

Parenteral injection of drug from the affected lots could lead to serious adverse events in areas where the particles lodge. Potential adverse events after intravenous administration include local damage to blood vessels in the lung, localized swelling, and granuloma formation. Intramuscular administration could result in foreign-body inflammatory response, with local pain, swelling and possible long term granuloma formation. Neurologic damage could result from intrathecal administration.

BACKGROUND: Methotrexate is an antimetabolite used in the treatment of neoplastic diseases, severe psoriasis, and rheumatoid arthritis, including polyarticular juvenile rheumatoid arthritis.

RECOMMENDATION: Customers and patients should immediately discontinue use of this product and patients should contact their physician or healthcare provider if they experience any problem that might be related to the use of this product. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Product lot numbers, label type, expiration dates, and recall instructions are listed in the Press Release.

October 12, 2010: Tylenol 8 Hour Caplets 50 Count: Recall Lot number: BCM155

ISSUE: McNeil is recalling TYLENOL 8 Hour caplets 50 count bottles to the retail level following a small number of complaints of a musty or moldy odor. The uncharacteristic odor is thought to be caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole.

BACKGROUND: This voluntary action is being taken as a precaution and the risk of adverse medical events is remote. To date, observed events reported to McNeil were temporary and non-serious. The product lot number for the recalled product can be found on the side of the bottle label.

RECOMMENDATION: Consumers should stop using the affected product and contact McNeil Consumer Healthcare, either at www.tylenol.com or by calling 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time, and Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time) for instructions about receiving a refund or product coupon. Consumers who have medical concerns or questions should contact their

healthcare provider.

October 15, 2010: CareFusion Corporation Alaris PC Units (Model 8015): Recall - Potential for Delay or Interruption of Therapy

ISSUE: Under certain wireless network conditions, a communication error can occur, which freezes the PC Unit screen. This error may result in a delay of therapy and inability to make programming changes to current infusions.

If the communication error occurs during infusion, infusion continues on all channels, as originally programmed, but cannot be modified. When this error occurs, stopping the infusion to make any modification or programming changes causes the PC unit to shut down resulting in a delay or interruption in therapy. This could lead to serious injury and/or death. These devices were manufactured from December 20, 2008 through September 8, 2009 and distributed from December 20, 2008 through June 28, 2010.

BACKGROUND: Electronic infusion pumps deliver controlled amounts of medications or other fluids to patients through an intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration.

RECOMMENDATION: If users experience the problem, they are to remove the device from service and contact the CareFusion Recall Center immediately. The corrective action will require a hardware update to all affected units. CareFusion does not require that the devices be returned.

October, 15, 2010: Excelsior Medical 5 ml Fill in 6 cc Prefilled Saline Flush Syringes: Recall - Potential Loss of Sterility

ISSUE: Routine internal testing conducted on this product found that some of these syringes may leak and lose sterility. This recall pertains only to syringes with the following product code numbers: E0100-50, 10056-1000, 10056-240, 14056-240, 910056-1000, and S5. Exposure to syringes with a sterility issue could result in systemic infection, which may lead to serious injury and/or death.

BACKGROUND: The Excelsior Disposable 5ml fill in 6 cc prefilled saline flush syringes are intended for the flushing of venous access devices and IV tubing.

RECOMMENDATION: Consumers who have 5ml fill in 6 cc saline pre-filled syringes manufactured by Excelsior Medical should immediately discontinue using these syringes and return them to the point of purchase.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program: 1) Complete and submit the report Online: www.fda.gov/MedWatch/report.htm; 2) Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Read the MedWatch safety alert, including a link to the Press Release, at: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/.

Coming Events

March 31, 2011: ISDH Indiana Healthcare Leadership Conference, *Improving Nutrition*, Indiana Convention Center, Indianapolis, Indiana. The agenda and registration information will be posted closer to the event.

October 27, 2011: ISDH Indiana Healthcare Leadership Conference, topic to be determined, Indiana Convention Center, Indianapolis, Indiana.

Best wishes.

Terry Whitson
Assistant Commissioner
Indiana State Department of Health