Federal Strike Force Targets Fraudulent Infusion Providers

In an August 20 press release, the U.S. Department of Justice (DOJ), Department of Health and Human Services (HHS), and the Centers for Medicare & Medicaid Services (CMS) announced a two-year demonstration project designed to identify and prevent fraudulent “providers of infusion therapy” from operating in South Florida (see “NHIA Responds to Crackdown” for more on the definition of infusion providers).

The project follows similar demonstration projects targeting fraudulent billing by suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) in South Florida and Southern California, and home health agencies in the greater Los Angeles and Houston areas. These geographic areas have shown a high frequency of Medicare-related fraud.

Since implementing the “phase one” Strike Force in Miami last March, prosecutors have filed 47 indictments charging 65 individuals and/or entities with health care fraud in schemes that collectively billed Medicare more than $345 million.

The Strike Force recently filed charges against Rita Campos and her company R and I Billing who submitted approximately $170 million in fraudulent medical bills on behalf of approximately 75 health clinics that purported to specialize in treating patients with HIV. Based on the claims filed by Campos, Medicare paid more than $100 million for these fraudulent services.
The investigation into R and I was prompted by spikes in billing detected in late 2003 and remains ongoing.

CMS will now require providers who operate in several South Florida counties to immediately resubmit applications to be a qualified Medicare provider. Those who fail to reapply within 30 days of receiving a notice will have their Medicare billing privileges revoked.

Providers that successfully complete the reapplication process may be subject to an enhanced review, including site visits, based on risk assessment. In addition, existing providers risk having their billing privileges revoked if they:

- Fail to report a change in ownership
- Are run by owners, partners, directors or managing employees who have committed a felony
- No longer meet each and every provider enrollment requirement

To read the CMS press release on this effort, go to www.nhia.org/docs/doh_doj_pr082007.pdf. To see a CMS fact sheet about the investigations and the demonstration project go to www.hhs.gov/news/facts/infusiontherapy.html.

**NHIA Responds to Fraud Crack Down**

The National Home Infusion Association (NHIA) is confident that the entities that committed the acts triggering the multi-agency investigation and the development of this demonstration project are not NHIA members, and on August 23 asked CMS to clarify whether home infusion therapy providers were implicated in the South Florida criminal investigation or the subsequent demonstration program.

The original materials released by the agencies did not describe the infusion providers or their settings of care that prompted this initiative, and early media stories following the announcement assumed that CMS was referring to home infusion therapy providers.

In response, CMS has amended the HHS Fact Sheet to make clear that neither the criminal investigation nor demonstration project involve infusion therapy providers who offer infusion in the home setting. Rather, the demonstration will be limited to clinics and solo practitioners located in South Florida that provide IV infusion therapy and/or intramuscular and subcutaneous injections in the office setting only.
NHIA believes that the constructive relationship we have developed with CMS over the past several years contributed to CMS’ quick response to our request. We will ensure that all Members of Congress who received the original notice from CMS regarding the demonstration program will receive CMS’ clarification that home infusion therapy providers are not involved.

"We commend CMS for responding quickly to clarify that home infusion therapy providers are not involved in this demonstration program," said Russell Bodoff, NHIA Executive Director. "We appreciate the constructive actions CMS has taken in this regard, and look forward to continuing our collaborative work with CMS on the array of coverage and quality of care issues pertaining to infusion therapy."

NHIA remains focused on improving Medicare coverage of home infusion therapy for Medicare beneficiaries. Additionally, NHIA strongly supports the passage of H.R. 2567, the Medicare Home Infusion Therapy Coverage Act of 2007, which would provide for meaningful coverage of home infusion therapy, as well as the development of essential quality standards.

To see the NHIA press release on CMS’ clarification, go to www.nhia.org/nhia_pr_083007.html.

FDA Issues Notice on Falsified Pump Repairs

On August 13, the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) issued a Preliminary Public Health Notification warning health care providers that purported repair, service, or testing may not have been performed on certain Baxter infusion pumps. The affected devices are the COLLEAGUE and FLO-GARD serviced in Baxter’s Phoenix, Arizona facility.

Baxter discovered falsified repair, test, and inspection data sheets, including electrical safety data, for some of the pumps and is investigating to determine the full extent of the falsification. The company has recalled the affected devices and has informed all customers to contact Baxter and to return the pumps for repeat inspection.

The specific units involved include:

- COLLEAGUE single channel volumetric infusion pumps (product codes 2M8151 and 2M8161) that have not received the upgrades cleared by FDA in February 2007
- COLLEAGUE triple channel volumetric infusion pumps (product codes 2M8153 and 2M8163) that have not received the upgrades cleared by FDA in February 2007
- FLO-GARD 620l volumetric infusion pump (product code 2M8063)
- FLO-GARD 6301 volumetric infusion pump (product code 2M8064)

Providers that have any of these devices are advised to remove them from service and return them to Baxter. Call 800-843-7867 for details.

To read the CDRH’s notice online, go to www.fda.gov/cdrh/safety/081307-baxter.html.

Joint Commission Appoints Home Care Leadership Positions

The Joint Commission recently announced the appointment of Debra Zak, Ph.D., R.N., as Executive Director of the Home Care Accreditation Program, and the promotion of Robert Floro, R.R.T., to Director, of the Home Care Accreditation Program, respectively. In these roles, Zak and Floro are responsible for promoting accreditation as an effective and valuable approach to improving the quality and safety of home care services.

Zak has worked at The Joint Commission for the past 15 years. Most recently, she served as Field Director of Surveyor Management and Development in the Division of Accreditation and Certification Operations. Prior to that, Zak worked as a Surveyor and as an Associate Director of Standards Interpretation.

She has a bachelor’s degree in nursing from Elmhurst College in Elmhurst, Illinois, and a master’s degree in Oriental medicine from Midwest College of Oriental Medicine in Chicago. Zak earned her doctorate from Guangzhou University of Traditional Chinese Medicine in Guangzhou, China.

Floro most recently served as the Senior Associate Director of The Joint Commission’s Home Care
Accreditation Program. Previously, he was a General Manager for American Home Patient in Central and Eastern Kentucky; and held several leadership positions with Respro Home Care in Kentucky, Ohio, Indiana, and Tennessee. As Director, Floro will concentrate on the durable medical equipment, prosthetics, orthotics, and supplies segment of home care accreditation.

Floro holds a bachelor’s degree in sociology from Eastern Kentucky University in Richmond, Kentucky, and an associate’s degree in respiratory care from the University of Kentucky in Lexington. He is a registered respiratory therapist.

“Debra and Bob’s combined experience within The Joint Commission and at health care organizations gives them a deep understanding of the home care field and the strategies necessary to support safe, high-quality services,” said Gina Val Zimmermann, Senior Executive Director of Business Development for the Joint Commission.

FDA Approves Cefotetan, Dextrose Injection Via Pump

The U.S. Food and Drug Administration (FDA) approved cefotetan for injection and dextrose for injection in the DUPLEX® Drug Delivery System.

Marketed by B. Braun Medical Inc., DUPLEX® is a dual-chamber IV container that stores the drug and diluent in separate compartments until the seal is broken just prior to administration. The system is also equipped with a unique barcode system that references the final admixture and can be used to reduce medication errors, automate patient charting, track inventory and facilitate reimbursement tracking.

“Cefotetan is a critical antibiotic, and we are committed to ensuring a safe and easy-to-use drug delivery system for cefotetan is available to hospitals nationwide,” said Rick Williamson, Director of Marketing, Drug Delivery, B. Braun Medical Inc. “The DUPLEX system is designed to alleviate pharmacist and caregiver workload while protecting patients from potential medication errors, reduce labor costs, and improve patient safety.”

FDA Approves Privigen™ Liquid IVIG

The U.S. Food and Drug Administration (FDA) has granted marketing approval to manufacturer CSL Behring for Privigen™ (Immune Globulin Intravenous (Human), 10% Liquid), an intravenous immunoglobulin (IVIG)
for treating patients diagnosed with primary immunodeficiency (PI). Privigen™ is also indicated for the treatment of chronic immune thrombocytopenic purpura (ITP) to rapidly raise platelet counts to prevent bleeding.

The drug is a 10-percent liquid preparation and is the only proline-stabilized IVIG that requires no refrigeration or reconstitution. CSL Behring plans to launch Privigen™ in the first quarter of 2008.

Privigen™ is contraindicated in patients with known anaphylactic or severe hypersensitivity responses to Immune Globulin (Human). Patients with severe selective IgA deficiency (IgA < 0.05 g/L) may develop anti-IgA antibodies that can result in a severe anaphylactic reaction. Such patients should only receive intravenous immune globulin with utmost caution and in a setting where supportive care is available for treating life-threatening reactions.

“Privigen™ is an exciting new offering to patients and health care professionals in the United States,” said Paul Perreault, Executive Vice President of Worldwide Commercial Operations at CSL Behring. “We see a strong demand for this drug and are pleased to be bringing it to patients and other valued customers.”

Abbreviations Pose Threat to Patient Safety
Although abbreviations in health care may be efficient, their use comes at the expense of patient safety, according to a new study published in the September 2007 issue of The Joint Commission Journal on Quality and Patient Safety. The findings support the use of—and possible additions to—a “Do Not Use” list of abbreviations that is part of Joint Commission National Patient Safety Goals.

The study, “the Impact of Abbreviations on Patient Safety,” collected and analyzed data through a retrospective review of errors resulting from abbreviations as reported to the United States Pharmacopeia’s national database for medication errors (MEDMARX®) from 2004 through 2006. Nearly five percent of all errors reported to MEDMARX® during this time period were attributable to abbreviations.

Notable findings in the study include:
• The most common abbreviation resulting in a medication error was the use of “qd” in place of “once daily,” accounting for 43.1 percent of all errors.

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The other most common abbreviations resulting in medication errors were “U” for units, “cc” for mL, “MSO4” or “MS” for morphine sulfate, and decimal errors.

Eighty-one percent of the errors occurred during prescribing, while errors during transcribing and dispensing were much less frequent, representing only 14 percent and 2.9 percent of errors, respectively.

Abbreviation errors originated more often from medical staff in comparison to nursing, pharmacy, other health care providers, and non–health care providers.

The three most common types of abbreviation-related errors were prescribing, improper dose/quantity, and incorrectly prepared medication.

"Accurate communication in the health care environment is a critical component of patient safety," explained the study’s lead author Luigi Brunetti, Pharm.D., a clinical assistant professor at the Ernest Mario School of Pharmacy at Rutgers University. "Our analysis confirms that abbreviation usage contributes to lapses in communication and may lead to patient harm."

ACHC Recognized in Inc. Magazine
The Accreditation Commission for Health Care, Inc., recently appeared in Inc. magazine’s listing of top 5,000 fastest-growing private companies in the country. The Raleigh, North Carolina-based accrediting body ranked nearly halfway up the list at number 2,308.

"The Inc. 5,000 provides the most comprehensive look ever at the most important part of the economy—the entrepreneurial part," said Inc. 5,000 Project Manager Jim Melloan. "Inc. proudly recognizes the importance of growing entrepreneurial companies that are changing with the business landscape. With the many challenges associated with building and operating a business, Inc. is keenly aware of what a tremendous achievement a spot on their list represents."

“I am just thrilled at where we have come over these past years," said ACHC President Tom Cesar. “We have a great team making these things happen.”

This year’s 5,000 listing is an extension of Inc.’s annual 500 list. To see the full listing, go to www.inc.com/inc5000.

From One to One Million
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