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WORKERS COMPENSATION

Meningitis outbreak adds to comp worry

Lawmakers criticize lack of oversight for drug compounding

By ROBERTO CENICEROS

The deadly meningitis outbreak in the United States is drawing greater scrutiny of drug compounding, which already is a concern in the workers compensation industry for certain pricing practices.

Managed care companies and pharmacy benefit managers that help treat workers compensation patients have taken precautions, such as reviewing case files to determine whether they need to help notify claimants that may have received tainted, injectable steroids linked to the outbreak that claimed at least 20 lives and caused some 250 confirmed meningitis cases as of last week.

While no formal link had been made that workers comp patients had received potentially contaminated injectable steroids made by New England Compounding Pharmacy Inc., several observers said it is likely the drugs reached some claimants because they were used to treat injuries that are common in the workplace.

"It would seem that there would be some work comp claimants just by virtue of the fact that people are being treated for back pain," said Jeffrey M. Adelson, a managing partner and workers comp defense attorney in the Santa Ana, Calif., office of Adelson, Testan, Brundo & Jimenez.

Several health care facilities that treat workers comp claimants are on a Centers for Disease Control and Prevention list of 76 sites in 23 states that received the compounded medication linked to the meningitis outbreak.

If a link is established to workers comp claimants, employers and insurers responsible for the original claim would be liable for additional medical expenses to treat the meningitis, Mr. Adelson said. The cost of treating meningitis and paying disability benefits, perhaps over a patient's lifetime, could turn a typical claim into a catastrophic case,



Officials say a fungus caused a meningitis outbreak linked to a drug compounding firm.

although workers comp payers could subrogate under a product liability argument, he said.

Compounding pharmacies prepare drugs to meet unique patient needs, such as when a patient requires a customized dose that is not available commercially.

But New England Compounding Pharmacy, which did business as the New England Compounding Center in Framingham, Mass., may have manufactured large quantities of compounded drugs, reportedly without individual prescriptions. NECC is at the center of state and federal investigations into the meningitis outbreak.

The FDA said that about 14,000 patients may have received injections of implicated drugs tied to NECC. About 97% of those patients have been notified.

In contrast to compounding small amounts for specific patients, manufacturing pharmaceuticals for mass distribution is subject to greater regulation.

"If you are manufacturing, then state and federal regula-

tions are much different than if you are just a compounding pharmacy, said Jim Andrews, executive vice president of pharmacy services at Healthcare Solutions Inc., a Duluth, Ga.-based pharmacy benefits manager.

Reacting to the meningitis outbreak, at least two federal lawmakers said they will introduce legislation to strengthen the Food and Drug Administration's authority over compounding.

"These pharmacies are intended to create customized versions of medicine for specific patients, not bulk production of medications," U.S. Rep. Rosa DeLauro, D-Conn., said in a statement about legislation she has introduced.

Rep. Edward J. Markey, D-Mass., criticized compounding pharmacies and said he, too, will introduce legislation calling for increased oversight.

But the Missouri City, Texas-based International Academy of Compounding Pharmacists, which represents more than 2,700 pharmacists, technicians and compounding firms, said in a statement that compounding is a valuable part of traditional pharmacy practices regulated by the FDA.

Compounding is necessary because of an ongoing, nationwide shortage of certain drugs, including some to treat work-related injuries, said Brian Carpenter, Tucson, Ariz.-based vice president of pharmacy benefit clinical services at Coventry Workers' Comp Services.

But recent years' growing use of compounded drugs has raised concern in the workers comp industry because of the

potential for prescribing providers to increase their revenue by avoiding state fee schedules that often place greater price controls on standard medications, he said. "While (compounding) is controlled by fee schedules, the rules are very, very loose," Mr. Carpenter said.

According to the "2011 Workers' Compensation Drug Trend Report" this year by St. Louis-based Express Scripts Inc., compounded medication costs have posted double-digit increases since 2008, with annual costs per user jumping 13.7% in 2011.

Yet many compounds prescribed to workers comp patients contain ingredients that are available as standard, commercial products, the report states. For example, several strengths of diclofenac, a nonsteroidal inflammatory drug, are available for about \$192 per prescription while compounded versions averaged \$720 in 2011.

Prescribing compounded topical creams and orally taken drugs is far more common in treating workers comp claimants than injectable products, such as those in the meningitis cases, sources said.

Unfortunately, patients who receive injections or infusions in a doctor's office face contamination fears just as compounding will undergo greater scrutiny, Mr. Andrews said. "There will be a period of public distrust of the products, rightly or wrongly. It's unfortunate, but I think the compounding industry will have to defend itself a bit on this for a while."

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