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PRESCRIPTION DRUGS: Lincare Contamination Leads To Investigation

To err may be human, but to track errors is the **Food and Drug Administration**.

The FDA wants to keep tabs on pharmacies' medical errors and other practices. In a March 13 pair of proposed regulations, the FDA says it will require bar codes on drugs and toughen requirements for reporting medication errors and adverse drug events. Both regs aim to prevent avoidable injuries from drug use.

All prescription drugs would require bar codes under the FDA plan, containing at least the drug's National Drug Code number, identifying drug, dosage form and strength. They might also contain lot numbers and expiration dates. The FDA envisions patients having their own bar codes, which pharmacy staff could scan before verifying the drug's bar code matched the patient's prescription.

The FDA predicts the rule could cut "dispensing and administration" medication errors in half, resulting in 413,000 fewer adverse events over the next 20 years.

The proposed bar-coding rule contains a 90-day comment period, and the agency says it expects to issue a final rule sometime this year, which would become effective three years after its release.

Separately, the FDA wants drug manufacturers to report actual medication errors and near-misses to the agency within 15 days. It would be up to pharmacists to report their errors to the pharmaceutical companies. The drug makers would have to report the errors even if the pharmacist caught the error before dispensing the wrong drug.

And the FDA wants reporting of "suspected adverse drug reactions that are serious and unexpected."

It's not clear whether the FDA's requirements would have helped in the recent case of **Med 4 Home Pharmacy**, a subsidiary of Clearwater, FL-based **Lincare Holdings**. According to the Kansas City Star, Med 4 Home distributed more than a million contaminated doses of albuterol compounded with ipratropium. The pharmacy then failed to recall the contaminated drugs properly.

Med 4 Home allegedly destroyed records and refused to allow a **Missouri Board of Pharmacy** inspector access to its compounding facilities on March 4. Lincare officials didn't return calls for this story.

The Star says the FDA is investigating Med 4 Home and Platte County Circuit Court issued a temporary restraining order preventing the pharmacy from compounding drugs or dispensing any compounded drugs through March 21, when a hearing was planned to evaluate the pharmacy's compliance with the Board's demands.

The pharmacy also must comply with requirements of sterility during the compounding process. It's not currently licensed to perform sterile compounding.

More than 19,000 patients nationwide may have received the contaminated doses, and another inhalant, budesonide, may also have been contaminated, officials said.

The pharmacy instituted a recall but told representatives not to explain to patients why it was recalling the drugs, and didn't notify prescribing physicians.

The pharmacy suspected the vials it shipped products in were contaminated, but the Pharmacy Board argued that all batches should have been recalled, not just the ones in the suspected vials.

Also, the budesonide batches sent in the suspect vials haven't been recalled.