South Florida Hospital News and Healthcare Report
THE REGION'S MONTHLY NEWSPAPER FOR HEALTHCARE PROFESSIONALS & PHYSICIANS

Legal Update – Food, Drug and Cosmetic Act Requirements for Prescription Drugs

The Food, Drug and Cosmetic Act (FDCA) regulates most aspects of the development, marketing and sales of prescription drugs. At the heart of the criminal prohibitions contained within the FDCA are the concepts of "adulteration" and "misbranding". "Adulteration" refers to the modification of a drug or device from its approved form. A drug or device is considered "misbranded" if the required approvals are not obtained from the FDA prior to the drug or device being introduced into interstate commerce. "Misbranding" also refers

to false or misleading information in the labeling or the failure to include required labeling. The FDCA, and related federal and state statutes, provide for criminal penalties for certain violations of the FDCA. Some of the types of prohibited conduct involving prescription drugs are described below.

1. Resale of Previously Billed Drugs

One commonly encountered violation involves the resale of prescription drugs that have been previously paid for by a healthcare benefit program typically Medicaid. The scheme often involves an unscrupulous pharmacy paying individuals for prescriptions that the pharmacy then bills to Medicaid as though the drugs were dispensed to the beneficiary. The pharmacy then resells the drugs, in bulk or singly, to other individuals out of the back door of the pharmacy.

2. Repackaging of Expired, Short Dated, Returned, Generic or Foreign Drugs

The repackaging of expired, short-dated, returned, generic or foreign drugs to conceal their true character results in the drugs being misbranded in violation of the FDCA.

3. Sale of Counterfeit Drugs

Although thankfully uncommon in the United States, occasionally counterfeit drugs are found in our drug market principally through Internet sales. The introduction of counterfeit drugs into interstate commerce violates the FDCA in that, at a minimum, the drugs would be misbranded.

4. Resale of Drug Samples

Pharmaceutical manufacturers frequently provide physicians with samples of prescription drugs. The Prescription Drug Marketing Act makes it unlawful for anyone to sell these drug samples. The maximum penalty for selling drug samples is surprisingly severe – 10 years imprisonment and a $250,000 fine.

5. Re-importation of U.S. Manufactured Drugs

Because of the fear that drugs that have been shipped overseas might become adulterated while outside of the controls that exist in the United States drug market, Congress made it unlawful for anyone other than the manufacturer of a drug to re-import a previously exported drug.

6. Breached of ” Own-use” (preferred pricing) provisions

Hospitals, closed-door pharmacies and some physicians may enter into reduced priced “own-use” contracts with drug manufactures for drugs to be used at their facilities. These “own-use” contracts generally prohibit the resale of the drugs purchased under the contract. A breach of this agreement can lead to fraud charges in certain circumstances.

7. Conclusion

To protect themselves, medical providers need to be aware of these prohibitions and need to take action to ensure that they and their staff do not violation the requirements of the FDCA unintentionally, or otherwise.
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