



Texas Department of Health

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March 26, 2001

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OPINION COMMITTEE

RQ-0371-80

FILE # ML-41941-01
I.D. # 41941

The Honorable John Cornyn
Attorney General of Texas
P.O. Box 12548
Austin, Texas 78711-2548

Dear General Cornyn:

I am writing to request an Attorney General's Opinion under authority of Texas Government Code § 402.042(b)(2).

Texas Health and Safety Code § 439.02(a) states:

- (a) A consulting pharmacist of a nursing home may select, from a supply of drugs due for destruction, certain drugs to be used for shipment to a foreign country as provided by this subchapter.
- (b) The supply of drugs due for destruction are those drugs accumulated because of the death of a resident of the nursing home or because a physician has ordered the use of the drug to be discontinued.

Texas Health and Safety Code § 439.022(a) states:

- (a) The Texas Board of Health shall adopt rules consistent with federal and state law to implement this subchapter. . . (emphasis added)

Question: Is the Texas Board of Health preempted by federal law from adopting rules under §439.02(a) and §439.022(a) of the Health and Safety Code except for physician samples?

Federal law seems to prohibit the recycling of prescription drugs except for physicians' samples. FDA Compliance Policy Guide No. 7132.08 states:

- 1) The sample drugs should be collected from the physician's office in their original unopened packages only by authorized collectors. The unopened samples should be placed in a carton, sealed, and sent to the responsible collection agency. (A responsible collection agency is one, which is registered with the Food and Drug Administration; licensed by the appropriate health agency, if required, in the State in which it operates; and maintains its operations under the supervision of a registered pharmacist or licensed physician.) The

drugs so collected should not be sent directly overseas.

- 2) The responsible collection agency should, under the supervision of a registered pharmacist or licensed physician at the agency's place of business, sort and screen all samples to eliminate all recalled, outdated and investigational drugs.
- 3) Sample drugs, after having been screened and sorted, should be sent in the original, unopened package by the agency to physicians and hospitals overseas.
- 4) Large bulk contributions of pharmaceuticals intended for overseas shipment may be subdivided, repackaged and labeled under the supervision of a registered pharmacist or licensed physician as indicated in (1 and 2) provided proper control procedures are observed and the repackaged product complies with the Food, Drug, and Cosmetic Act.
- 5) State laws which prohibit the operations provided for in these guidelines will take precedence thus if a State's law prohibits the collection of physicians samples these guidelines would be inapplicable in that State.

See also: 21 U.S.C. § 382(f); Prohibition of Export of Drug or Device and 21 U.S.C. § 381(e); Exports

FDA Compliance Policy Guidelines No. 7132.09 states that a pharmacist should not accept unused portions of prescriptions because there would no longer be any assurance of strength quality, purity or identity of the drugs.

- Texas Pharmacy Rules 22 TAC Part 15, § 291.8; Return of Prescription Drugs. This provision prohibits a pharmacist from accepting any unused prescription or drug.
- Minimum Licensure Standards For Nursing Homes, 25 TAC Part I § 145.21(a). Requires all discontinued or expired medications to be destroyed.
- Nursing Facility Requirements For Licensure and Medicaid Certification 40 TAC § 19.1504(h) Drug Security. Requires medications of deceased residents, medications which have passed the expiration date, and medications which have been discontinued to be disposed of according to federal and state laws or rules on a quarterly basis.

Your consideration of this request will be greatly appreciated. If you need additional information please contact the assigned staff attorney, Michael Greenberg, at (512) 458-7236.

Sincerely,



Charles E. Bell, M.D.
Executive Deputy Commissioner