DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Ch. II

Controlled Substances in Emergency Kits for Long Term Care Facilities

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Statement of Policy.

Summary: The Drug Enforcement Administration has received numerous requests from state licensing and regulatory boards, pharmaceutical associations, and professional organizations concerning the agency's policy for the use and handling of controlled substances in emergency kits for patients in Long Term Care Facilities (LT CF). The Drug Enforcement Administration has determined that an amendment to current regulations is not necessary or desirable, in that LT CF's are not controlled premises under Federal law. However, issuance of a Statement of Policy will provide the individual state licensing and regulatory boards with general guidelines under which they may, in turn, promulgate specific rules for the use of and handling of controlled substances in emergency kits for Long Term Care Facilities.

Additionally, this course of action should improve health care services to such patients and decrease the quantities of controlled substances which might otherwise accumulate at Long Term Care Facilities which federally are non-registered locations.

Date: Comments should be received on or before May 12, 1980.

Advisory: Send comments in triplicate to: Administrator, Drug Enforcement Administration, U.S. Department of Justice, 1405 Eye Street, Northwest, Washington, D.C. 20537, Attention: Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Ronald W. Buzzo, Chief, Compliance Division, Office of Compliance and Regulatory Affairs, Drug Enforcement Administration, 1405 Eye Street, Northwest—Room 518, Washington, D.C. 20537, Telephone (202) 633-1091.

Statement of Policy

The placement of emergency kits containing controlled substances in non-federal registered Long Term Care Facilities (LT CF) shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate:

A. The source from which a LT CF may obtain controlled substances for emergency kits. The source of supply must be a DEA registered hospital's clinic, pharmacy or practitioner.

B. Security safeguards for each emergency kit stored in the LT CF which include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

C. Responsibility for proper control and accountability of such emergency kits within the LT CF to include the requirement that the LT CF and the providing DEA registered hospital's clinic, pharmacy or co-practitioner maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of these controlled substances plus the requirement to take periodic physical inventories.

D. The emergency medical conditions under which the controlled substances may be administered to patients in the LT CF to include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.51.

E. Prohibited activities which may result in the state revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in a LT CF.

Date: April 1, 1980

Peter B. Massinger, Administrator.

[FR Doc. 80-10769 Filed 4-8-80; 8:45am]
BILLING CODE 4410-04-M