

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, and 1307

[Docket No. DEA-240P]

RIN 1117-AA75

Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: Because long term care facilities (LTCFs) generally do not have pharmacies on site and are not registered with DEA, they typically receive controlled substances prescribed for specific patients in 30 day supplies, although smaller supplies are sometimes used. As patients leave or their medication needs to be changed, the LTCFs accumulate stocks of excess controlled substances. The excess stocks can result in significant problems with waste and disposal and present opportunities for diversion of controlled substances. DEA is proposing changes to its existing regulations to allow, where State laws permit, for pharmacy installation of automated dispensing systems (ADSs) at LTCFs. Automated dispensing systems would allow dispensing of single dosage units and mitigate the problem of excess stocks and disposal.

DATES: Written comments must be postmarked on or before January 2, 2004.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion

Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

I. Background

Legal Authority

DEA enforces the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended. DEA regulations implementing this statute are published in Title 21 of the Code of Federal Regulations (CFR), Part 1300 to end. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical purposes. Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11-1308.15, and generally include narcotics, stimulants, depressants, hallucinogens, and anabolic steroids that have a high potential for abuse and dependency. DEA's regulations require that persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA, keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

Controlled Substances at Long Term Care Facilities (LTCFs)

Patients at LTCFs receive numerous medications, including controlled substances. Unlike hospitals, LTCFs are rarely DEA registrants. Patients at these facilities are usually seen by their personal physicians, who prescribe any necessary medication. These prescriptions are filled by retail pharmacies and delivered to the LTCFs for patients' use. Because LTCFs are not registrants and generally do not have physicians or pharmacists on staff, they may not order and maintain stocks of controlled substances to be dispensed under the order of a practitioner as occurs in hospitals. Instead, the LTCF holds the controlled substance medications that are dispensed by prescription to the specific patients by a provider pharmacy in a custodial manner for administration to the patient. Any controlled substance medications that are not ultimately

administered to the individual specific patient are waste that must be disposed of. Although DEA permits pharmacies to dispense a prescription for a LTCF patient on a daily or dosage unit basis rather than dispense the entire quantity prescribed, reimbursement rules under Medicare and Medicaid and other third party payors make daily dispensing financially unattractive for pharmacies; pharmacies are allowed a limited number of dispensing fees plus the calculated cost of the medication per month. As a consequence, pharmacies routinely dispense the entire prescription to the patient at once.

A result of this dispensing practice is that when patients leave the facility or their medications change, the LTCF is left with excess controlled substances, which must be disposed of to avoid diversion. Because they are not registrants, the LTCFs may not transfer the substances to either the pharmacy that supplied them or to a reverse distributor for disposal. The LTCF must dispose of the excess controlled substances directly.

Previous DEA Actions

DEA has frequently been asked to assist in resolving this matter. The principal concern has been to prevent the accumulation of controlled substances that are dispensed but not administered to the patient. DEA has attempted to address this problem through the establishment of partial dispensing provisions for Schedules II-V prescriptions (including unit-dose dispensing, if desired), to limit the quantity of controlled substances dispensed at one time and avoid waste if the treatment was changed or discontinued. According to the pharmacy industry, however, dispensing fees, reimbursement practices, and difficulties in educating practitioners regarding the need to prescribe controlled substances in anticipation of a patient's actual need for the controlled substance have, for the most part, precluded using that approach.

Current DEA Regulations

Although most LTCFs are not registered with DEA, DEA regulations allow a LTCF to register, if licensed by its State to handle controlled substances. DEA issues a registration in one of the following categories based upon the type of license/permit issued