

DEA is not opposed to making other options available to LTCFs and pharmacies, as long as they address the problems discussed in this proposal, maintain strict levels of security and accountability, and comply with Federal and State regulatory requirements.

Other Comments on the April 25, 2001 Notice

A number of commenters, including current ADS users, supported the option of using ADSs for controlled substances at LTCFs, believing they can reduce waste and disposal problems, eliminate opportunities for medication errors, improve patient care, and/or reduce diversion of controlled substances.

A number of commenters also suggested this was not a good idea, citing primarily one or more of the following reasons:

- ADSs are expensive to finance and maintain.
- State laws and regulations will need to be changed.
- Registration at each location would be burdensome and expensive.
- The logistics associated with use and maintenance of the systems are complicated.
- There are substantial security concerns. Commenters provided examples of where security issues (e.g., diversion, misdispensing) have arisen.
- ADSs do not represent a total solution to waste/disposal problems.

Several of these concerns are addressed elsewhere in this preamble. To the extent DEA does not specifically address some of these issues, DEA would reiterate that it recognizes this option will not work in all situations. However, DEA believes that ADS systems should be an *option* to be used where it does make sense and is otherwise permissible.

Medication Delivery Systems Currently Used by LTCFs

DEA is not suggesting that unit-dose delivery systems or other medication delivery systems that most LTCFs use be replaced. DEA recognizes that the cost of an automated dispensing system as well as other requirements associated with its use at a LTCF may not be warranted in many cases. Therefore, the use of an automated dispensing system for storage and dispensing of controlled substances to residents of LTCFs would be an option available to the provider pharmacy.

Specific Proposed Regulatory Changes

Current Federal law does not prohibit the use of ADSs for storage and dispensing of controlled substances at LTCFs where the LTCF itself is a DEA

registrant. However, to successfully implement the approach being proposed here requires several regulatory revisions:

- Section 1300.01 would be modified to include a definition of automated dispensing system.

- Section 1301.17 would be modified to incorporate an additional "special procedure" for the type of registrations that are the subject of this notice.

Specifically, retail pharmacies applying for a separate registration to operate an ADS at a LTCF will need to provide as part of their registration application an affidavit attesting to the existence of a State license, permit, or other authorization for activities at the LTCF.

- Section 1301.27 would be added to indicate that only retail pharmacies may operate automated dispensing systems at long term care facilities. The section would further indicate that a retail pharmacy must maintain a separate registration at each long term care facility location at which automated dispensing systems are installed and operated, and that if more than one retail pharmacy operates an automated dispensing system at a long term care facility, each retail pharmacy must maintain its own separate registration at that facility. Finally, this section indicates that retail pharmacies applying for separate registrations to install and operate automated dispensing systems at long term care facilities would be exempt from application fees for those separate registrations.

- Section 1304.04 would be revised to permit a registered retail pharmacy with one or more associated registrations at LTCFs to keep all records for those LTCF locations at the retail pharmacy site or other approved central location.

- Since the provider pharmacy would likely be ordering controlled substances for multiple LTCFs that it services, § 1307.11(b) which limits total distribution by a practitioner to 5 percent of all controlled substances dispensed in the course of a year would be amended to provide an exemption for this activity.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small business entities. This

proposed rule provides the option of using an automated dispensing system to dispense controlled substances to patients at long term care facilities.

Facilities which currently use automated dispensing systems for the dispensing of noncontrolled substances and, where permitted by DEA registration, for controlled substances report in industry literature that, while there are costs associated with the lease or purchase of an automated dispensing system, automated dispensing systems have the following benefits:

- Significantly reduce drug waste. Various studies over the past ten years have indicated that between 4 and 10 percent of medications at long term care facilities are wasted. Additional reports indicate that the use of an automated dispensing system reduces this waste by 90 percent.

- Significant cost savings for payors. As noted previously, automated dispensing systems have the potential to reduce the cost of medications dispensed because medications are dispensed in a "just in time" manner for administration rather than dispensing a larger quantity of medication less frequently, which can create waste.

- Reduce nursing and pharmacy labor costs. Nurses and pharmacy personnel no longer must prepare medications for dispensing to individual patients. Time is also saved by nursing staff due to the fact that medication administration records are now maintained electronically. Often, this time is then redirected to providing patient care.

- Reduce the potential for medication dispensing and administration errors. Automated dispensing systems provide greater accuracy in the dispensing and administration of medications.

Because the proposed rule does not require the use of automated dispensing systems, DEA believes that only pharmacies and LTCFs which find use of these systems cost-effective will adopt this approach.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is not a significant regulatory action because it does not impose costs above \$100 million a year or raise novel issues. Therefore, this action has not been reviewed by the Office of Management and Budget. Rather, this NPRM proposes to permit the installation of automated dispensing systems at long term care facilities by provider pharmacies, so long as state