

by a State and the authorized activities associated with the license/permit:

- **Retail pharmacy**—A pharmacy located on-site at the LTCF maintains stocks of controlled substances and a pharmacist dispenses patient-specific controlled substances to residents of the LTCF who have prescriptions for the substances.

- **Hospital/clinic**—The LTCF maintains institutional stocks of controlled substances for dispensing by a pharmacist for administration to residents under medication orders from a practitioner.

- **Mid-Level Practitioner**—Controlled substance activities are limited to those authorized by the individual State.

- **Practitioner**—An individual practitioner, such as the Medical Director of the LTCF, registers at the site of the LTCF and is responsible for the handling of controlled substances utilized at the LTCF.

Request for Information

On April 25, 2001, DEA published a notice in the **Federal Register** (66 FR 20833) soliciting comments and suggestions on the problem of excess controlled substances at LTCFs. Almost two dozen comments were received from a range of organizations and individuals, including State agencies, automated dispensing system (ADS) manufacturers, trade associations, and pharmaceutical providers. Information received in response to that notice is discussed below.

II. Discussion of the Proposed Rule

DEA's Proposal

To further address the issue of excess controlled substances in LTCFs, DEA is proposing to allow a provider pharmacy to register at the site of the LTCF and store controlled substances in an ADS. An ADS is conceptually similar to a vending machine. A pharmacy stores bulk drugs in the ADS in separate bins or containers and programs and controls the ADS remotely. Only authorized staff at the LTCF would have access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs would not be considered dispensed until the system provided them, drugs in the ADS would be pharmacy stock, not waste.

Specifically, DEA is proposing the definition of "automated dispensing system" as follows: "a mechanical system that performs operations or activities, other than compounding or

administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information."

The key elements of an automated dispensing system would be the following:

- State authorization for pharmacies to locate stock in the automated dispensing systems at the LTCF.

- Establishment through State regulation of the necessary and appropriate policies and protocols with respect to access to pharmacy stock by LTCF nursing personnel, ensuring secure storage of the controlled substances, transfer of the controlled substances from the primary pharmacy location to the LTCF site, and related issues.

- Issuance of a DEA registration to the provider pharmacy at the LTCF as a separate location, based on its current DEA registration and without additional application fees.

DEA is proposing to allow the use of automated dispensing systems as an option, not a requirement. DEA recognizes that there are reasons why ADSs may not work in many circumstances, but believes that some LTCFs will find ADSs a viable solution for preventing accumulation of excess controlled substances. This technology has a number of advantages, including the following:

- It can substantially reduce controlled substance waste, thereby providing significant cost savings to purchasers of controlled substances. It also can significantly reduce the time and other costs associated with maintaining patient medication stocks and disposal of excess stocks for LTCFs.

- With single-dose dispensing, secure storage, and controlled access, it can help to control drug inventory and increase accountability.

- With an increasing amount of controlled substances in use as the LTCF population grows, it can help control the opportunities for drug diversion.

- It recognizes advancements made in technology and provides the option of using the most current technology in a broader array of circumstances.

- With the current pharmacist shortage, it relieves dispensing pharmacists of a number of manual steps involved in drug handling.

- For consulting pharmacists in their responsibilities for drug regimen review, it provides enhanced tools with a full range of accurate data available online because the data are captured automatically.

III. Use of Automated Dispensing Systems

Existing State Laws and Regulations

To implement this solution, States would need to grant approval (*i.e.*, a license, permit, or other authorization) for the provider pharmacy to function at the location of the LTCF using an ADS, and establish policies and procedures regarding system security, access, and the like. States could define such an operation so as to avoid the many peripheral requirements of traditional pharmacies such as sinks, reference books, etc.

Other Options DEA Considered

As solicited by the April 25, 2001, request for information, one commenter suggested that LTCFs should be able to obtain a limited registration for purposes of contracting with reverse distributors for waste disposal. DEA believes that, while this option has merit on the issue of disposal, it does not address control of waste and it potentially imposes additional disposal costs on LTCFs. Further, LTCFs would need state authorization to handle controlled substances in the manner envisioned here before DEA could issue them a DEA registration. In addition, LTCFs would be required to comply with DEA recordkeeping and reporting requirements.

Another suggestion was to address directly the problem of excess medications being sent to facilities in the first place. Specifically, the commenter suggested that practitioners' routine medication orders not be sent to the LTCF unless actually necessitated by the patient. A related suggestion was to change reimbursement standards that are, at least in part, responsible for the current situation. Unfortunately, these are not issues that DEA is empowered to address.

Yet another suggestion was to authorize limited permit pharmacies at LTCFs 2–3 days per week. It is unclear to DEA how this option of a "part-time" pharmacy resolves the current problems.

Finally, there were various suggestions about a pharmacy maintaining controlled substances as floor stock at LTCFs as an alternative to an ADS. DEA notes that this option would still require someone to be registered at the LTCF (either the pharmacy or the LTCF itself). The significant concern with this option is the need to maintain accountability and security for the controlled substances, which DEA believes is much easier to do with an ADS.