

regulations permit such installation. The use of automated dispensing systems by long term care facilities provides another alternative to address the problem of accumulation of surplus controlled substances at long term care facilities. DEA believes that persons choosing to utilize this method of dispensing controlled substances to patients at long term care facilities may realize cost savings. More importantly to DEA, the use of such systems should reduce the accumulation of excess controlled substances at these facilities, thereby reducing the potential for diversion of these controlled substances.

Paperwork Reduction Act

This rule proposes that a retail pharmacy currently registered with DEA would be required to apply for separate registration at the location of the long term care facility at which it intends to install and operate an automated dispensing system. Application for registration is made using currently existing DEA registration forms (DEA Form 224 for registration and 224A for registration renewal). DEA estimates that approximately 100 persons per year will apply for registration to operate automated dispensing systems at long term care facilities. Therefore, DEA is revising its OMB-approved information collection (OMB 1117-0014) to reflect this increased burden due to this program change.

Further, within this rulemaking DEA is proposing that at the time of application for this separate registration at the long term care facility by the retail pharmacy, the applicant must include with their application for registration (DEA Form 224) an affidavit as to the existence of State authorization to operate the automated dispensing system at the long term care facility. DEA has provided a format for the affidavit as part of its proposed regulations. This affidavit is exempt from the requirements of the Paperwork Reduction Act (5 CFR 1320.3(h)(1)).

Executive Order 12988

This proposed rule meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rule does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$113,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Prescription drugs.

21 CFR Part 1307

Drug traffic control.

For the reasons set out above, 21 CFR parts 1300, 1301, 1304, and 1307 are proposed to be amended as follows:

PART 1300—DEFINITIONS [AMENDED]

1. The authority citation for Part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

2. Section 1300.01 is proposed to be amended by adding a new paragraph (b)(45) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(45) The term automated dispensing system means 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.

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES [AMENDED]

3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 956.

4. § 1301.17 is proposed to be revised by redesignating paragraph (c) as paragraph (d) and adding new paragraph (c) to read as follows:

§ 1301.17 Special procedures for certain applications.

* * * * *

(c) If at the time of application for a separate registration at a long term care facility, the retail pharmacy has been issued a license, permit, or other form of authorization from the appropriate State agency to install and operate an automated dispensing system for the dispensing of controlled substances at the long term care facility, the applicant must include with his/her application for registration (DEA Form 224) an affidavit as to the existence of the State authorization. Exact language for this affidavit may be found at the DEA Diversion Control Program web site. The affidavit must include the following information:

(1) The name and title of the corporate officer or official signing the affidavit;

(2) The name of the corporation, partnership or sole proprietorship operating the retail pharmacy;

(3) The name and complete address (including city, state, and Zip code) of the retail pharmacy;

(4) The name and complete address (including city, state, and Zip code) of the long term care facility for which DEA registration is sought;

(5) Certification that the named retail pharmacy has been authorized by the state Board of Pharmacy or licensing agency to install and operate an automated dispensing system for the dispensing of controlled substances at the named long term care facility (including the license or permit number, if applicable);

(6) The date on which the authorization was issued;

(7) Statements attesting to the following:

(i) The affidavit is submitted to obtain a Drug Enforcement Administration registration number;

(ii) If any information is false, the Administration may immediately suspend the registration for this activity