

dispose of any controlled substances on hand.

#### **Why Is DEA Publishing This Action as an Interim Final Rule?**

As discussed previously, the goal of the NPRM was to give codified status to reverse distributors. While DEA initially proposed doing this by registering reverse distributors in the manufacturer category, comments on the NPRM made it clear that this approach would adversely affect the existing industry (e.g. by subjecting reverse distributors to certain EPA and FDA regulations). By registering reverse distributors as distributors, DEA accomplishes its original goal in a manner that is consistent with the intent of the NPRM and with public comments on the NPRM. Also, this approach is beneficial rather than detrimental to the entire controlled substances industry. However, recognizing the time which has elapsed between publication of the NPRM and this action, as well as the growth and evolution of the reverse distributor industry during that time, DEA has determined that, rather than publishing final regulations on this issue, it is in the best interest of industry that DEA publish an interim final rule. Publishing an interim final rule will permit further comment from the affected industry, ensuring that final regulations appropriately address industry evolution and concerns.

#### **Summary**

In summary, the registration and other requirements for reverse distributors under this interim final rule are the same as those currently imposed on distributors and the same as currently imposed on reverse distributors under MOUs; Registration requirements under existing 21 CFR 1301.13; Security requirements under existing 21 CFR 1301.71 and 1301.72; Inventory requirements under existing 21 CFR 1304.11; Recordkeeping requirements under existing 21 CFR 1304.22; Reporting requirements under existing 21 CFR 1304.33 (ARCOS reports); Order form requirements under existing 21 CFR 1305.08 (Persons entitled to fill order forms). In some cases these rules have been modified to apply specifically to reverse distributors. In addition, DEA is amending 21 CFR 1307.11 and 1307.12 to clarify that registrants can transfer ("distribute") controlled substances to a reverse distributor, even if the registrant is not registered as a distributor. As a result of DEA's decision to classify reverse distributors as a new category of registration, instead of as a manufacturer, proposed 21 CFR 1303.12 on quotas is not applicable.

The closed system of distribution established under the CSA for controlled substances relies on certain fundamental principles, including registration, security, and accountability (i.e., inventories, recordkeeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing the potential for diversion. The fact that reverse distributors engage in a unique activity within the controlled substances chain and are faced with certain challenges that other registrants do not normally encounter does not override the fundamental principals of DEA's controls. Reverse distributors must register, provide security, and maintain accurate records for all controlled substances in their possession. However, the regulatory structure does provide some flexibility and, where possible, DEA has made adjustments to address some of the problems the industry has encountered, including use of a separate category of registration and application of the inventory requirements for dispensers and researchers.

Because of the length of time since the NPRM was published and the evolving nature of this industry, DEA is using an interim final rule to give an additional opportunity for comment. DEA will consider comments on the appropriateness and the practical application of these rules to current industry practice and will be flexible where possible in developing final rules.

#### **Application for Registration for Reverse Distributors**

As has been previously noted in this rulemaking, persons wishing to conduct reverse distributor activities must register with DEA to do so. To apply for registration, persons must complete a DEA Form 225, Application for Registration. To renew a DEA registration, persons must complete a DEA Form 225a, Application for Registration Renewal. As DEA has not yet issued updated forms specifically referencing the reverse distributor business activity, persons wishing to register as reverse distributors must choose the distributor business activity on the form and then must attach a written statement signed by the person signing the registration or registration renewal application acknowledging that the applicant is conducting or wishes to conduct reverse distributor activities.

#### **Regulatory Certifications**

##### *Regulatory Flexibility Act*

The Deputy Assistant Administrator hereby certifies that this interim final rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. Therefore, no regulatory flexibility analysis is required.

##### *Executive Order 12866*

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). DEA has determined that this rule is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

##### *Executive Order 12988*

The Deputy Assistant Administrator further certifies that this regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

##### *Executive Order 13132*

This rulemaking 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 \$100,000,000 or more 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 of 1996*

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-