

controlled substances by specific individuals? Can losses be attributed to unique activities which may take place involving the controlled substances?

Individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether unexplained losses of controlled substances are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances.

What Specific Regulations Does This Rulemaking Propose To Amend?

Specifically, this rulemaking proposes the amendment of 21 CFR 1301.74(c) and 1301.76(b) to include the factors listed above as factors which a registrant should consider when determining whether a loss is significant and, thus, must be reported to DEA. DEA encourages registrants to use other criteria, as well as those factors listed above, which they have found to be useful in the evaluation of losses of controlled substances when determining whether such losses are significant, but is proposing the provision of these factors as the minimum which registrants should consider.

Guidance Regarding Breakage, Spillage and Other Explained Loss of Controlled Substances

What Is Required of a DEA Registrant When Breakage or Spillage Occurs?

DEA has encountered instances in which registrants have attempted to report spillages or explained losses of controlled substances on a DEA Form 106. The breakage, spillage or other witnessed controlled substance losses do not require the immediate notification of DEA. If controlled substance containers are broken or damaged, or controlled substances spilled, the substances are not considered "lost" because they can be accounted for. When breakage, spillage or damage of controlled substances occurs, the affected controlled substances must be disposed of according to DEA requirements.

If there is breakage, spillage or other damage to controlled substances, but the controlled substances are still recoverable, then the registrant has two options for disposing of the controlled substances. The registrant may dispose of the controlled substances by either (1) Contacting their local DEA field office and receiving permission from that office to dispose of the controlled substances pursuant to 21 CFR 1307.21,

or (2) the registrant may send those controlled substances to a firm registered with DEA to handle returns/disposals.

If the registrant receives permission from DEA to dispose of the controlled substances pursuant to 21 CFR 1307.21, then that registrant must complete a DEA Form 41, Registrants Inventory of Drugs Surrendered, explaining the circumstances of the breakage. Two individuals who witnessed the breakage, spillage or damage must sign the DEA Form 41, indicating what they witnessed. Registrants must submit three copies of the DEA Form 41 to their local DEA field office (21 CFR 1307.21(a)(1)). Registrants are also required to maintain a copy of the DEA Form 41 in their records.

If the registrant sends the controlled substances to a DEA registered disposer, then the registrant must complete the necessary paperwork showing the distribution of the damaged controlled substances to the registered disposer.

If the breakage or spillage is clearly observed but the controlled substances are not recoverable, then the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records, indicating what they witnessed. These records must be maintained in the registrant's files.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator 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 entities. This regulation seeks to clarify existing DEA regulations regarding the reporting of thefts and losses of controlled substances. No new recordkeeping or reporting requirements are proposed in this rulemaking.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget. This rulemaking merely seeks to clarify existing DEA regulations, policies and procedures.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

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-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1301

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

For the reasons set out above, 21 CFR part 1301 is proposed to be amended as follows:

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

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

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

2. Section 1301.74 is amended by revising paragraph (c) to read as follows: