

supplier will have the records necessary to maintain the closed system of control while allowing the supplier to take advantage of its own system of distribution.

A copy of the economic analysis for this proposed rule can be obtained by contacting the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297 or on the Diversion Control Program web site, <http://www.deadiversion.usdoj.gov>. DEA solicits comments on the economic analysis and the reasonableness of the assumptions.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980, Federal agencies must evaluate the impact of rules on small entities and consider less burdensome alternatives. As discussed in the previous section DEA has conducted a preliminary cost benefit analysis on this proposal. As part of that analysis, DEA evaluated the impact on small entities. DEA has determined that this rule would affect a substantial number of small entities. DEA estimates that about one third of the manufacturers and hospitals, 40 percent of clinics and pharmacies would meet the Small Business Administration definition of "small business." Practitioners and narcotic treatment programs are all assumed to be small.

The proposed rule, however, would reduce the burden for registrants over time. DEA, in developing its approach, considered the impact on small businesses and has tried to design an approach that will impose the least costs on businesses consistent with meeting the mandate of the CSA. DEA considered developing an electronic Form 222, which would have been the most direct way to meet the mandate of the CSA for a form issued by DEA. DEA worked extensively with the regulated community throughout the development of this proposal, and realized that requiring the use of a specific form would force businesses to alter their established electronic ordering systems to accommodate a form that might not be consistent with their software platforms. DEA decided that such changes would be unnecessarily costly. Instead, DEA has proposed a system for digital signatures that can be added to any software platform and, therefore, would require limited reprogramming.

DEA, as part of its economic analysis, considered the costs of the existing system and the proposed approach for small entities. The annualized costs of the Form 222 system for the smallest

entities (clinics with less than \$100,000 in revenues), are less than 1.45 percent of annual revenues; for these clinics, the annual costs of the proposed rule are about 0.15 percent of annual revenues. For most small entities affected by the rule, the cost of the electronic system will be less than 0.1 percent of revenues or sales. Consequently, the Acting 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.

A copy of the small business analysis for this proposed rule, which is section 7 of the economic analysis, can be obtained from the Diversion Control Program web site or by contacting the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

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.

Paperwork Reduction Act

The Department of Justice (DOJ), Drug Enforcement Administration (DEA) has submitted the following information collection requests to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. Under the Paperwork Reduction Act, DEA is required to estimate the burden hours and other costs of any requirement for recordkeeping and reporting over a three-year period. Therefore, DEA is proposing the revision of an existing collection of information *U.S. Official Order Forms for Schedules I and II Controlled Substances (Accountable Forms), Order Form Requisition*, and the creation of a new collection of information *Reporting and Recordkeeping for Digital Certificates* under the Paperwork Reduction Act of 1995. This process is conducted in accordance with 5 CFR

1320.11. The Information Collection Request has been submitted to the Office of Management and Budget for review under section 307 of the Paperwork Reduction Act. Comments should be submitted to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for the Department of Justice.

Written comments and suggestions are requested from the public and affected agencies concerning the proposed collections of information.

Comments should address one or more of the following four points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, if applicable, or additional information, please contact Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

Overview of U.S. Official Order Forms for Schedules I and II Controlled Substances (Accountable Forms), Order Form Requisition Information Collection

(1) Type of information collection: Revision of existing collection.

(2) The title of the form/collection: U.S. Official Order Forms for Schedule I and II Controlled Substances (Accountable Forms), Order Form Requisition.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form No.: DEA Form 222, U.S.

Official Order Forms for Schedule I and II Controlled Substances (Accountable Forms).