

Section 1311.20 proposes to specify the application requirements for obtaining a digital certificate.

Section 1311.30 proposes to provide the requirements for using and storing a digital certificate.

Section 1311.40 proposes to specify the number of certificates needed.

Section 1311.45 proposes to specify when a new certificate must be obtained.

Section 1311.50 proposes to provide requirements for registrants that grant power of attorney authority.

Section 1311.55 proposes to specify requirements for recipients handling electronic orders prior to filling them.

Section 1311.60 proposes to specify software requirements for handling electronic orders.

Section 1311.65 proposes recordkeeping requirements.

Incorporation by Reference

The following standards are proposed to be incorporated by reference:

- FIPS 140-2, Security Requirements for Cryptographic Modules.
- FIPS 180-1, Secure Hash Standard.
- FIPS 186-2, Digital Signature Standard.

These standards are available from the National Institute of Standards and Technology, Computer Security Division, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899-8930 and are available at <http://csrc.nist.gov/>.

V. Required Analyses

Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), DEA must determine whether a regulatory action is "significant" and, therefore, subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or

adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal government or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Since the proposed rule would not impose costs of \$100 million a year and will in fact reduce the burden on DEA registrants, DEA does not consider this rule to be an economically significant regulatory action as defined. However, this rule has been reviewed by the Office of Management and Budget.

DEA did, in the course of developing the proposed rules, consider the costs and benefits of the proposed rule.

DEA registration figures indicate that approximately 101,000 registrants are likely to issue or fill orders. Those issuing orders include pharmacies, hospitals and clinics, practitioners, teaching institutions, exporters, researchers, chemical analysts, narcotic treatment programs, distributors, and manufacturers. Distributors, manufacturers, and importers fill most orders for Schedule I and II controlled substances. The universe of digital certificate holders is larger than the universe of registrants because everyone with power of attorney authority will need to obtain a digital certificate. For purposes of this analysis, DEA assumed that manufacturers and distributors would have an average of six certificate holders per registered location; pharmacies, hospitals, clinics, teaching institutions, and exporters, an average of two. The four chain pharmacies that process orders centrally for their 9,900 pharmacies are assumed to have six

certificate holders each. All other registrants are assumed to have a single person associated with a registration seeking a digital certificate. Overall, DEA estimates that approximately 160,000 digital certificates will be requested.

The primary costs in the current system are completing the Form 222 and mailing it to the supplier, requisitioning Forms 222, entering the data from the form, annotating the forms, logging and tracking forms, archiving the annotated forms, and sending them to DEA. Table 1 shows the unit time estimates and costs for mailing orders and requisitions (Operations and Maintenance (O&M) costs). Table 2 presents the estimate to total annual cost of the Form 222 system.

TABLE 1.—UNIT TIME AND FIXED COST ASSUMPTIONS FOR FORM 222

Activity	Hours	O&M cost
Purchaser:		
Requisition forms	0.05	\$0.37
Complete and express ship orders	0.25	11.25
Complete and mail orders	0.25	0.37
Annotate file ..	0.05	
Log and file forms	0.033	
Supplier:		
Annotate forms	0.083	
Enter and file forms	0.25	
Log and track forms, prepare for mailing to DEA	9	17.25

TABLE 2.—TOTAL ANNUAL HOURS AND COSTS FOR THE FORM 222 SYSTEM

Activity	Total hours	Total labor cost	Total capital and O&M cost	Total
Completing and mailing orders	1,334,648	\$100,232,000	\$5,853,000	\$106,085,000
Requisitioning Form 222s	3,467	260,000	26,000	286,000
Annotating and filing	2,224,413	99,364,000	405,000	99,768,000
Sending orders to DEA	85,428	3,008,000	164,000	3,172,000
Total	3,647,956	202,864,000	6,447,000	209,311,000

The proposed system of digital certificates would impose initial

implementation costs and on-going costs. People seeking a digital certificate

would have to complete the application, generate keys, learn how to use the