

like the Commission to reconcile ESign's policy with the statutes they administer. The Commission will act shortly to provide interpretative guidance and, where appropriate, propose or adopt rules consistent with ESign. These releases will be published separately in the **Federal Register**.

Because ESign does not generally apply to information required to be filed with government agencies, the Commission is not currently contemplating any changes to its existing filing rules as a result of ESign. Filers should therefore continue to follow current filing rules.

Dated: February 28, 2001.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1304, 1305, 1306, 1311

[DEA-214A]

RIN 1117-AA60, 1117-AA61

Electronic Commerce: Electronic Orders for Schedule I and II Controlled Substances; Electronic Prescriptions for Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is publishing this Advance Notice of Proposed Rulemaking to formally notify the interested public of DEA's intent to publish Notices of Proposed Rulemaking regarding two electronic initiatives. The first electronic initiative (RIN 1117-AA60) will propose regulations to provide DEA registrants with the option of ordering Schedule I and II controlled substances electronically in a manner consistent with the requirements of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). The regulations will propose that this electronic system may also be used for ordering controlled substances in Schedules III, IV and V. The second electronic initiative (RIN 1117-AA61) will propose regulations to permit DEA registered prescribers to electronically write, sign and transmit prescriptions. These proposed regulations would be an addition to, not a replacement of, the

existing rules. Through these electronic initiatives, DEA will be proposing regulations consistent with the Government Paperwork Elimination Act (Pub. L. 105-277) (GPEA) and the Electronic Signatures in Global and National Commerce Act (Pub. L. 106-229) (E-Sign). Publication of this Advance Notice of Proposed Rulemaking also responds to the requirements of E-Sign which state that for a Federal agency which has announced, proposed, or initiated a rulemaking proceeding to prescribe a regulation responding to E-Sign on or before March 1, 2001, the effect of E-Sign's record retention provision is delayed until June 1, 2001.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Why Is DEA Publishing This Advance Notice of Proposed Rulemaking?

DEA is publishing this Advance Notice of Proposed Rulemaking to formally notify the interested public that DEA intends to publish, in the near future, two Notices of Proposed Rulemaking regarding two electronic initiatives DEA has undertaken. These electronic initiatives, and their accompanying regulations, will permit DEA to comply with GPEA and E-Sign, while ensuring appropriate controls over the ordering and prescribing of controlled substances in order to prevent diversion. DEA is publishing this Advance Notice of Proposed Rulemaking to comply with Sec. 107(b)(1)(B) of Pub. L. 106-229 which states: "DELAYED EFFECT FOR PENDING RULEMAKINGS. If on March 1, 2001, a Federal regulatory agency or State regulatory agency has announced, proposed, or initiated, but not completed, a rulemaking proceeding to prescribe a regulation under section 104(b)(3) with respect to a requirement described in subparagraph (A), this title shall be effective on June 1, 2001, with respect to such requirement."

What Electronic Initiatives Does DEA Intend To Propose?

DEA expects to publish, in the near future, two Notices of Proposed Rulemaking to propose new regulations for two electronic initiatives. The first electronic initiative (RIN 1117-AA60) will propose regulations to provide DEA registrants with the option of ordering Schedule I and II controlled substances

electronically in a manner consistent with the requirements of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). The regulations will propose that this electronic system may also be used for controlled substances in Schedules III, IV and V. The second electronic initiative (RIN 1117-AA61) will propose regulations to permit DEA registered prescribers to electronically write, sign and transmit prescriptions. These proposed regulations would be an addition to, not a replacement of, the existing rules.

What Actions Has DEA Already Undertaken Regarding These Electronic Initiatives?

In 1999, PEC Solutions, Inc. (PEC) (formerly Performance Engineering Corporation) was selected by DEA's Office of Diversion Control to analyze mandated, paper-based regulatory processes and to design and develop proposed concepts for public key infrastructures (PKIs) that would allow DEA and industry the option of using the current paper-based systems or electronic formats to order or prescribe controlled substances. As part of the project methodology, DEA/PEC sought input from persons within the interested industries to gain an understanding of processes involved in these regulated activities. DEA has published relevant documents and information regarding both electronic initiatives on the Office of Diversion Control's web site, at <http://www.dea.diversion.usdoj.gov>, link to "Electronic Commerce Initiatives". Finally, DEA has held a number of public meetings (announced on DEA's web site and in letters to the industry) to detail progress of the projects, answer questions and solicit further input. DEA continues to provide information on its web site regarding project documents, updates and future meetings.

Rulemaking Analyses and Notices

Due to the preliminary nature of this document, information to complete the rulemaking analyses and notice is unavailable, and thus, not contained in this Advance Notice of Proposed Rulemaking.

Dated: February 27, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

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