

SUMMARY: This regulation implements the new threshold requirements and mail order reporting requirements of the Methamphetamine Anti-Proliferation Act of 2000 (MAPA), which was enacted on October 17, 2000. DEA is amending its regulations to reduce the thresholds for pseudoephedrine and phenylpropanolamine for retail distributors and for distributors required to submit mail order reports. Also, DEA is amending its regulations to require mail order reports for certain export transactions. DEA is codifying exemptions from the mail order reporting requirements for certain distributions to nonregulated persons and certain export transactions. This rule is consistent with the intent of MAPA to prevent the diversion of drug products to the clandestine manufacture of methamphetamine and amphetamine, and simultaneously reduce the industry reporting burden.

EFFECTIVE DATE: November 6, 2003.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

What Is DEA's Legal Authority for This Rule?

DEA implements the Controlled Substances Act (21 U.S.C. 801-971), as amended by the Chemical Diversion and Trafficking Act, the Domestic Chemical Diversion Control Act, the Comprehensive Methamphetamine Control Act, and the recent Methamphetamine Anti-Proliferation Act (Pub. L. 106-310, 114 Stat. 1101), among others. DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (21 CFR) parts 1300 to end. The regulations are designed to prevent the diversion of controlled substances and listed chemicals to illegal purposes.

MAPA, which is part of the Children's Health Act of 2000, amends the Controlled Substances Act (CSA) to reduce the retail and mail order thresholds for pseudoephedrine and phenylpropanolamine (PPA), to include certain export transactions under the mail order reporting requirement, and to provide certain exemptions from the mail order reporting requirement. This rule implements the Congressional mandate of MAPA.

Why Is DEA Publishing a Final Rule?

An agency may find good cause to exempt a rule from the provisions of the Administrative Procedure Act (5 U.S.C.

553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. Most of the requirements of MAPA were set out in such detail as to be self-implementing. Therefore the changes in this rulemaking primarily provide conforming amendments to make the language of the regulations consistent with that of the law. Hence, DEA finds it unnecessary to publish for public notice and comment.

Specifically, Title XXXVI, Methamphetamine Anti-Proliferation Act, Section 3652 of the Children's Health Act, "Mail Order Requirements," amends 21 U.S.C. 830(b)(3)(D) to exempt certain distributions and export transactions of ephedrine, pseudoephedrine, and phenylpropanolamine and drug products containing them from the monthly mail order reporting requirement as follows [emphasis added]:

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, **shall not** be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than 2 solid dosage units or the equivalent of 2 dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 102(46). [21 U.S.C. 802(46)]

(iii) Distributions of drug products to a resident of a long term care facility (as the term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 1004 [21 U.S.C. 954] or 1018 [21 U.S.C. 971] which are subject to a waiver granted under section 1018(e)(2) [21 U.S.C. 971(e)(2)].

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this title * * *

Editor's Note: This excerpt of the amendment is published for the convenience of the reader. The official text is published at 21 U.S.C. 830(b)(3)(D).

MAPA also specifically reduces the threshold for drug products containing pseudoephedrine and phenylpropanolamine from 24 grams to 9 grams of pseudoephedrine or phenylpropanolamine as base. MAPA further establishes a new factor in determining a regulated transaction—a package size of 3 grams of pseudoephedrine base or phenylpropanolamine base. The language in Title XXXVI, Section 3622 of the Children's Health Act of 2000, "Reduction in Retail Sales Transaction Threshold for Non-Safe Harbor Products Containing Pseudoephedrine or Phenylpropanolamine," clearly establishes without opportunity for discussion the new requirements. It amends 21 U.S.C. 802(39)(a)(iv)(II) to read as follows [emphasis added]:

(II) the quantity of ephedrine, pseudoephedrine, phenylpropanolamine, or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine by retail distributors or by distributors required to submit reports by section 310(b)(3) of this title [21 U.S.C. 830(b)(3)] **shall be** 9 grams of pseudoephedrine or 9 grams of phenylpropanolamine in a single transaction and sold in package sizes of not more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base; * * *

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Under the circumstances, there is no discretion for deviation from the changes made by MAPA. Therefore, DEA is implementing these conforming amendments to the regulations through a final rule.

Do the Thresholds Apply to All Retail Distributors and All Distributors Required To Submit Mail Order Reports?

MAPA mandated that effective October 17, 2001, both the reduction of the 24 gram transaction threshold to 9 grams and the addition of the 3 gram package size threshold for pseudoephedrine and phenylpropanolamine drug products apply to all retail distributors and all persons required to submit mail order reports under 21 U.S.C. 830(b)(3).

At the retail level, all drug products containing pseudoephedrine or phenylpropanolamine that do not meet