

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes additional controlled airspace at Walden-Jackson County Airport, Walden, CO.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9R, Airspace Designations and Reporting Points, signed August 15, 2007, and

effective September 15, 2007 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM CO, E5 Walden, CO [New]

Walden-Jackson County Airport, CO
(Lat. 40°45'0" N., long. 106°16'17" W.)

That airspace extending upward from 700 feet above the surface within a 5-mile radius of Walden-Jackson County Airport, and within 4 miles each side of the 342° bearing from the airport extending from the 5-mile radius to V524 northwest of the airport.

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Issued in Seattle, Washington, on January 3, 2008.

Clark Desing,

Manager, System Support Group, Western Service Area.

[FR Doc. E8–844 Filed 1–17–08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1309

[Docket No. DEA–294P]

RIN 1117–AB09

Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Combat Methamphetamine Epidemic Act of 2005 (CMEA), which was enacted on March 9, 2006, requires DEA to establish an assessment of annual need for the importation and manufacture of ephedrine, pseudoephedrine, and phenylpropanolamine. Because of the new CMEA mandates for importation, import quotas, and production quotas for these chemicals, DEA must revise its registration provisions. The changes made by the CMEA render current DEA regulations inadequate for two reasons. First, although DEA registers bulk manufacturers of the three chemicals in the United States and importers of the bulk chemicals, some of those chemicals are distributed to non-registered companies that process them into prescription drugs. Under the Controlled Substances Act, section 826, production quotas are available only to registered manufacturers. DEA cannot

meet the CMEA mandate to establish annual need and import quotas, and then issue individual quotas for each of the chemicals unless all manufacturers manufacturing or procuring the chemicals and manufacturing drug products that contain the chemicals are registered as manufacturers, even if the distribution of the final drug products is not regulated. DEA also must know the quantity of prescription drug products containing the three chemicals being imported. Without this information, DEA would not be able to determine an assessment of annual need for these chemicals. Any person importing prescription drug products containing any of the three chemicals must register although the distribution of these products would not be subject to DEA regulation.

Second, persons currently registered to import, distribute, or dispense controlled substances who manufacture drug products using ephedrine, pseudoephedrine, or phenylpropanolamine, are not necessarily registered to do so. This must also be changed so that controlled substance registrants will only receive a waiver from the requirement of separate chemical registration if they engage in the same activity for both lawfully marketed drug products containing List I chemicals and controlled substances (as is already the case for bulk manufacture, imports, and exports.) In this way, any registrant that must obtain a quota to manufacture or procure one or more of the chemicals will be a registered manufacturer, as required by the CSA.

Were DEA not to issue this rule, it would have no mechanism to issue production or import quotas for persons handling prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. If these persons were not required to register, there would be no mechanism by which they would be permitted to apply for production or import quotas. Therefore, these persons would have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

Accordingly, DEA is proposing to amend its registration regulations to ensure that every location that manufactures or imports one of these chemicals or drug products that contain ephedrine, pseudoephedrine, or phenylpropanolamine is a DEA registered manufacturer or importer. These amendments will make it possible to establish the system of quotas and assessment of annual needs for the manufacturing that Congress

mandated for ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before March 18, 2008.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-204" on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the

public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington DC 20537 at (202) 307-7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture, distribution, import, and export of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified

as List II chemicals may be used to manufacture controlled substances.

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109-177). Much of CMEA is self-implementing; the provisions related to importation of ephedrine, pseudoephedrine, and phenylpropanolamine, import quotas, manufacturing quotas, and procurement quotas became effective on March 9, 2006.

CMEA Requirements and Impact on Registration

CMEA amended the CSA to include ephedrine, pseudoephedrine, and phenylpropanolamine in 21 U.S.C. 826 (Production quotas for controlled substances) and section 952(a) (Importation of controlled substances). Congress essentially imposed the same requirements for importation of ephedrine, pseudoephedrine, and phenylpropanolamine as are imposed on narcotic raw materials—crude opium, poppy straw, concentrate of poppy straw, and coca leaves. That is, imports of ephedrine, pseudoephedrine, and phenylpropanolamine are prohibited except for such amounts as the Attorney General (DEA by delegation) finds to be necessary to provide for medical, scientific, or other legitimate purposes. Congress also imposed the same requirements on the manufacture of ephedrine, pseudoephedrine, and phenylpropanolamine as are established for Schedule I and II controlled substances. That is, Congress mandated the establishment of a total need for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These requirements apply equally to products containing these three List I chemicals as they do to the List I chemicals themselves.

Controlled substances are subject to a closed system of controls that ensures that no person may manufacture, distribute, import, export, or dispense unless that person is a DEA registrant, or exempted from the requirement of registration. Production of Schedule I and II controlled substances is limited to the quantity that DEA has determined is required to meet the legitimate medical, scientific, research, and industrial needs of the United States; for

lawful export requirements; and for establishment and maintenance of reserve stocks (21 U.S.C. 826(a)). After DEA establishes the total annual need, DEA issues individual manufacturing and procurement quotas to manufacturers; under section 826, quotas may be issued only to registered manufacturers. Manufacturers may not produce or purchase more of a substance than is available under their individual quotas. Under the CSA, "manufacture" is defined to include all of the following:

- The manufacturing of a substance or chemical in bulk, either by extraction from raw materials, chemical synthesis, or a combination of extraction and chemical synthesis.
- The processing of the substance or chemical into products, such as drugs in dosage form.
- The packaging or repackaging of the processed substances or chemicals or labeling or relabeling of containers holding the chemicals.

Until the passage of CMEA, chemical importers were required to notify DEA of imports of ephedrine, pseudoephedrine, and phenylpropanolamine before or at the time of importation under 21 U.S.C. 971. DEA had no authority to limit the importation or manufacture of ephedrine, pseudoephedrine, and phenylpropanolamine, except the ability to suspend a proposed import under 21 U.S.C. 971 on the ground that it may be diverted to the clandestine manufacture of a controlled substance. Most of the ephedrine, pseudoephedrine, and phenylpropanolamine used in the United States is imported rather than manufactured domestically, although at least one company in the United States manufactures the chemicals in bulk. The three chemicals are used to produce drug products lawfully marketed under the Federal Food, Drug and Cosmetic Act (FFD&CA), many of which are prescription drugs. DEA has not subjected these prescription drug products to all List I chemical regulatory requirements because they are available only in response to a prescription and are stored in and dispensed at pharmacies. These chemicals are also used in over-the-counter (OTC) drug products (lawfully marketed under the FFD&CA). These products have been widely used in the illegal manufacture of methamphetamine and amphetamine. CMEA defined these OTC drug products as scheduled listed chemical products. DEA has regulated the distribution, import, and export of scheduled listed chemical products.

DEA, in 1995, first imposed registration requirements on firms that manufacture, distribute, import, and export List I chemicals. Although section 822 of the CSA states that any person who manufactures or distributes a controlled substance or List I chemical must register with DEA, DEA limited chemical registration for manufacturers to firms that manufacture to distribute List I chemicals. Some manufacturers were not required to register under the "manufacture for distribution" policy. Those that manufactured and chemically consumed and transformed all of the chemical in their own processes; those that purchased List I chemicals in bulk and manufactured prescription drug products that contain a List I chemical; and those that repackaged or relabeled prescription drug products that contain a List I chemical were not required to obtain a DEA chemical registration. Firms that manufacture a List I chemical in bulk and distribute to wholesalers or to other manufacturers were already required to register and file reports with DEA. Firms that manufacture scheduled listed chemical products (nonprescription/OTC drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine) also distribute those products, were already required to obtain a DEA chemical registration.

As a consequence of the "manufacture for distribution" policy, firms that manufactured prescription drugs containing ephedrine, pseudoephedrine, and phenylpropanolamine were not required to register because distributions of the prescription drug products were not regulated. DEA, in § 1309.22, listed only four activities involving List I chemicals that required registration: Retail distributing, non-retail distributing, importing, and exporting. On the application for registration form, firms were required to indicate whether they were seeking to be registered as manufacturers or distributors (e.g., wholesalers), but the regulation did not distinguish between those who manufacture to distribute and those who simply distribute. In addition, in § 1309.24, DEA waived the chemical distribution registration requirement for firms that manufacture or distribute drug products lawfully marketed under the FFD&CA containing the three chemicals for any firm that is registered to manufacture, distribute, or dispense a controlled substance. Note that this waiver (from the requirement to obtain a separate DEA chemical registration) was only provided for drug products containing a listed chemical which is in final packaged/labeled form

which is lawfully marketed under the FFD&CA. Drug products not in final packaged/labeled form were not provided this waiver. For example, an importer of bulk tablets containing a listed chemical, intended for a drug product marketed in the United States, would still have to obtain a chemical importer registration, and would not be able to use their controlled substance registration for such activity.

The waiver does not apply in the reverse; a firm that handles controlled substances must register for the applicable controlled substance activity even if it is already registered to conduct the same activity with List I chemicals.

As a consequence of these decisions, there are firms manufacturing drug products lawfully marketed under the FFD&CA containing ephedrine, pseudoephedrine, or phenylpropanolamine that are not registered with DEA at all because they do not handle controlled substances and the only products they produce containing the three chemicals are prescription drugs. There are also firms that manufacture scheduled listed chemical products, but only distribute or dispense controlled substances. Because they are registered as controlled substance distributors or dispensers, they are not currently required to register as chemical manufacturers. Finally, there may be some firms that are not registered that import prescription drug products that contain the three chemicals.

Because of the new CMEA mandates for importation, import quotas, and production quotas for these chemicals, DEA is proposing to revise its registration provisions. The changes made by the CMEA render current DEA regulations inadequate for two reasons. First, although DEA registers bulk manufacturers of the three chemicals in the United States and importers of the bulk chemicals, some of those chemicals are distributed to non-registered companies that process them into prescription drugs. Under the CSA section 826, production quotas are available only to registered manufacturers. DEA cannot meet the CMEA mandate to establish an annual need and import quotas, and then issue individual quotas for each of the chemicals unless all manufacturers manufacturing or procuring the chemicals and manufacturing drug products that contain the chemicals are registered as manufacturers, even if the distribution of the final drug products is not regulated. DEA also must know the quantity of prescription drug products containing the three chemicals being

imported; without this information, DEA would not be able to determine an assessment of annual need for the chemicals. Any person importing prescription drug products containing any of the three chemicals must register although the distribution of these products would not be subject to DEA regulation.

The second inadequacy is that the existing language allows a controlled substance distributor or dispenser to avoid registration as a chemical manufacturer if they manufacture scheduled listed chemical products or other products containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D). (DEA notes that there may be a limited number of drug products containing List I chemicals other than ephedrine, pseudoephedrine, and phenylpropanolamine which meet this description.) This provision must also be changed so that controlled substance registrants will not need to obtain a chemical registration only if they engage in the same activity for both drug products containing List I chemicals and controlled substances as is already the case for bulk manufacture, imports, and exports. In this way, any registrant that must obtain a quota to manufacture or procure one or more of the chemicals will be a registered manufacturer, as required by the CSA.

DEA recognizes that this change will require some manufacturers and locations to register that had not previously been subject to DEA regulations; other registrants will be required to obtain separate registrations for chemicals and controlled substances. The proposed new requirements,

however, are both consistent with the statutory language on registration and the CMEA amendments and with the intent of the CMEA requirements to establish a system of quotas for the manufacture of these three chemicals and the products that contain them. Without these changes, DEA would not be able to meet the CMEA mandates. In addition, without these changes, companies that manufacture and import prescription drug products containing the three chemicals would not be able to purchase the chemicals legally nor would the assessment of annual needs reflect their requirements.

Explanation of DEA Categories of Registration and Effect of This Rule Regarding DEA Registration

As noted above, the CSA defines the term "manufacture" to include the physical manufacture of a chemical or product, as well as the packaging, labeling, repackaging, and relabeling of that product (21 U.S.C. 802(15)).

If this rule is finalized as proposed, persons who manufacture or import ephedrine, pseudoephedrine, or phenylpropanolamine, or who manufacture or import a product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or who plan to engage in such activities, would be required to register with DEA if they are not already registered for the appropriate business activity. As required by the CSA, registration is location-specific; a person must obtain a registration for each principal place of business at one general physical location where controlled substances or List I chemicals are handled. If a person manufactures controlled substances at one location and drug products

containing ephedrine, pseudoephedrine, or phenylpropanolamine at another location, the person would be required to obtain a separate registration for each location. Under the waiver previously described in this rulemaking, persons who are currently registered as controlled substances manufacturers at a location where drug products containing these List I chemicals are also manufactured would not be required to register separately to conduct the same activity, manufacturing, with these List I chemicals. A controlled substances registration for that one physical location would cover both the manufacturing of controlled substances and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, at that location. Controlled substances manufacturers would, however, be required to identify to DEA the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine they handle as part of their next registration renewal. DEA notes that the manufacture of bulk List I chemicals requires a separate chemical registration; this is not a change from existing regulations.

However, if a person manufactures a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine at a location, but is registered to conduct other (nonmanufacturing) activities with controlled substances at that location (e.g., distribution), the person would need to obtain a List I chemical manufacturing registration for the location. The following table indicates the changes in registration requirements being proposed for various business activities.

Current	Proposed
Chemical Manufacturers (No Controlled Substances)	
All bulk manufacturers of List I chemicals must register unless all of the chemical produced is consumed internally and is not available for use in products.	No change.
Manufacturers of scheduled listed chemical products register if distribute.	All manufacturers of drug products containing List I chemicals* would register.
Manufacturers of prescription products** containing List I chemicals do not register.	
Chemical Distributors	
Distributors of List I chemicals and scheduled listed chemical products register.	No change.
Distributors of prescription products** containing List I chemicals do not register.	
Chemical Importers and Exporters	
Importers of List I chemicals and scheduled listed chemical products register.	Importers of List I chemicals and all drug products containing List I chemicals* would register.
Importers of prescription products** containing List I chemicals do not register.	

Current	Proposed
Exporters of List I chemicals and scheduled listed chemical products register. Exporters of prescription products** containing List I chemicals do not register.	No change.
Manufacturers and Distributors of Controlled Substances and Drug Products Containing List I Chemicals	
Manufacturers of both controlled substances and drug products containing List I chemicals may register as only controlled substance manufacturers.	No change.
Manufacturers of drug products containing any List I chemical* who distribute or dispense controlled substances may register for only their controlled substance activity. A separate registration for the chemical activity is permissible.	Manufacturers of drug products containing any List I chemical* would register as manufacturers. If they distribute or dispense controlled substances they would register separately for those activities.
Distributors of both controlled substances and drug products containing List I chemicals may register as only controlled substance distributors.	No change.
Importers/Exporters of Controlled Substances and Drug Products Containing List I Chemicals	
Importers of both controlled substances and drug products containing List I chemicals register as controlled substance importers.	No change.
Exporters of both controlled substances and drug products containing List I chemicals register as controlled substance exporters.	No change.
Manufacturers, Distributors, Importers, and Exporters of Bulk List I Chemicals	
Manufacturers, distributors, importers, and exporters of bulk List I chemicals register, regardless of whether they handle controlled substances.	No change.

* "Drug products containing List I chemicals" refers to scheduled listed chemical products or other products containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D). Such drug products must be in packaged/labeled form as required under the FFD&CA for lawful marketing.

** "Prescription products," for purposes of this chart, refers to "any transaction in a List I chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act * * *" (21 U.S.C. 802(39)(a)(iv)). To comply with the marketing and distribution requirements of the Federal Food, Drug, and Cosmetic Act for prescription drugs, such drugs must be packaged and labeled in accordance with the Federal Food, Drug and Cosmetic Act as prescription drugs.

Proposed Requirements of This Rule

DEA is proposing that a person who manufactures or imports a prescription drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine would be required to comply with the following:

Registration. Any person who manufactures or imports a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or proposes to engage in the manufacture or importation of a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine, would be required to obtain a registration under the CSA (21 U.S.C. 822 and 958). Regulations describing registration for List I chemical handlers are set forth in 21 CFR part 1309.

A separate registration is required for manufacturing, distribution, importing, and exporting, except that a person registered to manufacture or import a List I chemical or a product containing ephedrine, pseudoephedrine, or phenylpropanolamine may distribute that List I chemical or drug product without obtaining a separate registration to do so. A separate registration is required for each principal place of

business at one general physical location where the List I chemicals are manufactured, distributed, imported, or exported by a person (21 CFR 1309.23).

As a result of the change, any person manufacturing or importing a prescription drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine would become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who would be newly subject to the registration requirement to complete and submit an application for registration and for DEA to issue registrations for those activities immediately. Therefore, to allow continued legitimate commerce, DEA is proposing to establish in § 1309.25 a temporary exemption from the registration requirement for persons desiring to engage in manufacturing or importing prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, provided that DEA receives a properly completed application for registration on or before 30 days from the date of publication of a Final Rule in the **Federal Register**. The temporary exemption for such

persons will remain in effect until DEA takes final action on their application for registration.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, will remain in effect. Additionally, the temporary exemption does not suspend applicable Federal criminal laws relating to these chemicals, nor does it supersede State or local laws or regulations. All manufacturers and importers of ephedrine, pseudoephedrine, or phenylpropanolamine, or any product containing any of these three List I chemicals, must comply with applicable State and local requirements in addition to the CSA regulatory controls.

Importation. All persons importing ephedrine, pseudoephedrine, or phenylpropanolamine, or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine would be required to comply with all requirements regarding importation.

Records and Reports. The CSA (21 U.S.C. 830) requires certain records to be kept and reports to be made involving listed chemicals. Regulations describing recordkeeping and reporting

requirements are set forth in 21 CFR part 1310. A record must be made and maintained for two years after the date of a regulated transaction involving a List I chemical. Each regulated bulk manufacturer of a regulated mixture must submit manufacturing, inventory, and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers producing the chemicals solely for internal consumption are not required to submit this information; internal consumption does not include using the chemical to produce drug products. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

Under 21 CFR 1310.05, regulated persons are required to report to DEA any regulated transaction involving an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that causes the regulated person to believe that the listed chemical will be used in violation of the CSA. Regulated persons are also required to report to DEA any proposed regulated transaction with a person whose description or other identifying information has been furnished to the regulated person. Finally, regulated persons are required to report any unusual or excessive loss or disappearance of a listed chemical.

Security. All applicants and registrants must provide effective controls against theft and diversion of chemicals as described in 21 CFR 1309.71.

Administrative Inspection. Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of ephedrine, pseudoephedrine, or phenylpropanolamine, or products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.

Section by Section Analysis of Proposed Rule Changes

DEA is proposing to amend §§ 1309.11 and 1309.12 to replace "manufacture for distribution" with "manufacture." In addition, in both sections, DEA is proposing to remove references to retail distributors. In amendments to 21 U.S.C. 823(h) the CMEA expressly stated that distributors of scheduled listed chemical products at

retail are not required to register under the Controlled Substances Act. To avoid confusion, DEA decided to address all registration revisions related to CMEA implementation in this rulemaking.

Section 1309.21 is proposed to be revised to state that every person who manufactures or proposes to manufacture a List I chemical or a drug product containing a List I chemical must register. The change would require manufacturers of prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine to register even though they are not required to register to distribute or export the products. DEA is also proposing to add a table to the section, similar to the table in § 1301.13 on controlled substance registration requirements, to summarize the requirements for each business activity. As discussed above, this revision would not alter the registration requirements for bulk manufacturers of List I chemicals and for manufacturers of scheduled listed chemical products.

Section 1309.22 is proposed to be revised to remove retail distributing as a registration activity and to add manufacturing. As explained above, CMEA explicitly states that retail distributors of scheduled listed chemical products are not required to register. DEA is also proposing to add a new paragraph to state that a person registered to manufacture a List I chemical is authorized to distribute that chemical under the manufacturing registration. The registrant may not distribute, under a manufacturer's registration, any List I chemical that is not covered in the manufacturing registration. This limitation parallels the existing limitation for importers.

In § 1309.24 paragraph (b) is proposed to be revised to clarify that a person who manufactures or distributes a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D) is exempted from registration only if registered to conduct the same activity with controlled substances. Paragraph (c) is proposed to be revised to clarify that a person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D) is exempted from registration only if registered to conduct the same activity with controlled substances. Paragraph (e) waiving registration for retail distributors is proposed to be removed because CMEA statutorily does not

require them to register. The remaining paragraphs (f) through (l) would be redesignated (e) through (k). DEA notes that the waiver of the requirement of registration continues for bulk manufacturers who manufacture and consume all of the List I chemical internally.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the provisions of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Combat Methamphetamine Epidemic Act of 2005 amended the Controlled Substances Act to require production quotas for manufacturers handling the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. CMEA also authorized the Attorney General (DEA by delegation), to establish import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. The Controlled Substances Act requires that quotas be issued to registrants. Were DEA not to issue this rule, it would have no mechanism to permit the registration of persons handling prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. If these persons were not permitted to register, there would be no mechanism by which they would be permitted to apply for production or import quotas. Therefore, these persons would have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

This rule proposes to codify provisions necessary for implementation of the Combat Methamphetamine Epidemic Act. As discussed further below, DEA has examined the potential impacts of this rule. DEA has no basis for estimating the number of firms that may be small, but given the definition of small entities, it is likely that a substantial number of the new registrants will be small. The cost of compliance, however, would not impose a significant economic burden. The only cost is the \$2,293 registration fee for manufacturers, and the \$1,147 registration fee for importers, respectively. The recordkeeping and reporting requirements can be met using existing business and manufacturing records. The security provisions are general and require the registrant to provide effective controls and procedures to guard against theft and diversion of List I chemicals. Any

manufacturer approved by the FDA and complying with good manufacturing practices or currently registered to handle controlled substances will have internal controls that meet this requirement. The smallest pharmaceutical firms (with 1 to 4 employees) had an average value of shipments of \$824,000 in 2002 (\$886,000 in 2007 dollars, based on GDP). Even for these firms, which are unlikely to be producing the covered drug products, the \$2,293 registration fee would represent less than 0.3 percent of sales and, therefore, is not a significant burden. Therefore, this rule will not have a significant economic impact on a substantial number of small entities.

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). It has been determined that this is "a significant regulatory action." Therefore, this action has been reviewed by the Office of Management and Budget. As discussed above, this action is necessary to implement statutory provisions. DEA has, nonetheless, reviewed the potential costs.

DEA has a limited basis for determining the number of manufacturers of prescription drug products that will need to obtain a DEA registration for the first time. DEA reviewed a list of pseudoephedrine products and ephedrine prescription drug products and identified 230 firms based on their labeler codes. Of all firms identified, 164 do not appear to be registered with DEA as manufacturers and 95 are not registered as either manufacturers or controlled substance distributors. The firms currently registered to manufacture controlled substances may not manufacture List I chemical drugs at the same locations. Seventy firms are currently registered as controlled substance distributors. There may be some firms that import prescription drug products that are not now registered to import either controlled substances or List I chemicals. DEA estimates that approximately 200 firms may have to obtain a new DEA registration. As noted above, the only cost imposed by the rule is the registration fee of \$2,293 for the registration of each manufacturing location, and \$1,147 for each importing location. The total cost of these rule changes will be less than \$500,000. The cost to individual firms is relatively small, compared with their revenues. The benefit of the rule is that it will make it possible for DEA to meet the

statutory mandate to assess the annual need for the chemicals accurately and provide manufacturers with the quotas they need to continue to produce drug products containing the three chemicals. As DEA discussed throughout this rulemaking, the Controlled Substances Act provides that quotas may only be issued to registrants. Were DEA not to issue this rule, it would have no mechanism to permit the registration of persons handling prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. If these persons were not permitted to register, there would be no mechanism by which they would be permitted to apply for production or import quotas. Therefore, these persons would have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

Paperwork Reduction Act

This Notice of Proposed Rulemaking would require that certain persons who were not previously registered with DEA obtain a registration to handle the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Specifically, persons manufacturing prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine were not previously required to register, but now would be required to obtain a registration so that they may be eligible to apply for individual quotas for these List I chemicals. Additionally, importers of prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine who were not previously registered as List I chemical importers would be required to register so that they may be eligible to apply for import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. DEA estimates that approximately 200 firms may have to obtain a new DEA registration. DEA assumes that these firms complete the registration application electronically, with each application taking 15 minutes to complete. The receipt of these additional applications increases the hour burden by 50 hours annually. Therefore, DEA is proposing to revise an existing approved information collection, "Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration Under Domestic Chemical Diversion Control Act of 1993" (OMB # 1117-0031), to reflect the increase in population associated with this rule.

Further, DEA is proposing to amend the forms associated with the existing approved information collection "Application for Registration (DEA Form 225) and Application for Registration Renewal (DEA Form 225a)" (OMB # 1117-0012) to include a listing of all List I chemicals on the application forms. Currently, controlled substances registrant applicants, who use these forms to apply for DEA registration, are not required to identify the List I chemicals they handle. Without this identification, it is not possible for these persons to apply for individual quotas for these chemicals. The addition of the List I chemicals will allow persons to identify which chemicals they handle. New applicants would be required to identify the List I chemicals they handle upon their initial application; persons renewing their registration will identify the chemicals at the time of their renewal. This information must merely be verified for each succeeding renewal. Thus, the addition of this list will not have a measurable effect on the time needed to complete the application. Therefore, DEA is not proposing to revise the collection itself, but rather is proposing to make changes only to the application forms themselves.

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

Written comments and suggestions from the public and affected agencies concerning the information collection-related aspects of this rule are encouraged. Your 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.

Overview of Information Collection 1117-0031

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

(2) *Title of form/collection:* Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration Under Domestic Chemical Diversion Control Act of 1993.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

Form Number: DEA Forms 510 and 510a.

Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: business or other for-profit.

Other: Not-for-profit, government agencies.

Abstract: The Domestic Chemical Diversion Control Act requires that manufacturers, distributors, importers, and exporters of List I chemicals which may be diverted in the United States for the production of illicit drugs must register with DEA. Registration provides a system to aid in the tracking of the distribution of List I chemicals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA estimates that 2,776 persons respond to this collection annually. DEA estimates that it takes 30 minutes for an average respondent to respond when completing the application on paper, and 15 minutes for an average respondent to respond when completing an application electronically. This application is submitted annually.

(6) *An estimate of the total public burden (in hours) associated with the collection:* DEA estimates that this collection has a public burden of 927 hours annually.

Form	Number of respondents	Total burden hours
DEA-510 (paper)	286	143
DEA-510 (electronic) ..	478	119.5
DEA-510a (paper)	644	322
DEA-510a (electronic) ..	1,368	342
Total	2,776	926.5

If additional information is required, contact: Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Executive Order 12988

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

Executive Order 13132

This rulemaking does not 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 \$120,000,000 or more (adjusted for inflation) 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.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 1309

Administrative practice and procedure; Drug traffic control; Exports; Imports; Security measures.

For the reasons set out above, 21 CFR part 1309 is proposed to be amended as follows:

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 958.

2. Section 1309.11 is revised to read as follows:

§ 1309.11 Fee amounts.

(a) For each application for registration or reregistration to manufacture the applicant shall pay an annual fee of \$2,293.

(b) For each application for registration or reregistration to distribute, import, or export a List I chemical, the applicant shall pay an annual fee of \$1,147.

3. Section 1309.12 is revised to read as follows:

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture, distribute, import, or export, the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) Payments should be made in the form of a credit card; a personal, certified, or cashier's check; or a money order made payable to "Drug Enforcement Administration." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

4. Section 1309.21 is revised to read as follows:

§ 1309.21 Persons required to register.

(a) Unless exempted by law or under §§ 1309.24 through 1309.26, the following persons must annually obtain a registration specific to the List I chemicals to be handled:

(1) Every person who manufactures or imports or proposes to manufacture or import a List I chemical or a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) Every person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under § 1300.02(b)(28)(i)(D) of this chapter.

(b) Only persons actually engaged in the activities are required to obtain a

registration; related or affiliated persons who are not engaged in the activities are not required to be registered. (For example, a stockholder or parent

corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(c) The registration requirements are summarized in the following table:

SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS

Business activity	Chemicals	DEA forms	Application fee	Registration period (years)	Coincident activities allowed
Manufacturing ...	List I, Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510 Renewal—510a	\$2,293 2,293	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
Distributing	List I, Scheduled listed chemical products.	New—510 Renewal—510a	1,147 1,147	1	
Importing	List I, Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510 Renewal—510a	1,147 1,147	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
Exporting	List I, Scheduled listed chemical products.	New—510 Renewal—510a	1,147 1,147	1	

5. Section 1309.22 is revised to read as follows:

§ 1309.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing of List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) Distributing of List I chemicals and scheduled listed chemical products.

(3) Importing List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(4) Exporting List I chemicals and scheduled listed chemical products.

(b) Except as provided in paragraphs (c) and (d) of this section, every person who engages in more than one group of independent activities must obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24 through 1309.26.

(c) A person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

(d) A person registered to manufacture any List I chemical shall be authorized to distribute that List I chemical after manufacture, but no other chemical that the person is not registered to manufacture.

6. In § 1309.23 paragraph (a) is revised to read as follows:

§ 1309.23 Separate registration for separate locations.

(a) A separate registration is required for each principal place of business at one general physical location where List

I chemicals are manufactured, distributed, imported, or exported by a person.

* * * * *

7. Section 1309.24 is revised to read as follows:

§ 1309.24 Waiver of registration requirement for certain activities.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if the agent or employee is acting in the usual course of his or her business or employment.

(b) The requirement of registration is waived for any person who manufactures or distributes a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of “regulated transaction” in § 1300.02(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance.

(c) The requirement of registration is waived for any person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of “regulated transaction” in § 1300.02(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance.

(d) The requirement of registration is waived for any person who only distributes a prescription drug product containing a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter.

(e) The requirement of registration is waived for any person whose activities

with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste disposal.

(f) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).

(g) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited solely to the distribution of Lugol’s Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer’s packaging of one fluid ounce (30 ml) or less.

(h) The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

(i) If any person exempted under paragraph (b), (c), (d), (e), or (f) of this section also engages in the distribution, importation, or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for the activities, as required by § 1309.21 of this part.

(j) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a waiver granted under paragraph (b), (c), (d), (e), or (f) of this section pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and §§ 1309.51 through 1309.55 of this part. In considering the revocation or suspension of a person's waiver granted pursuant to paragraph (b) or (c) of this section, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to 21 U.S.C. 824 is warranted.

(k) Any person exempted from the registration requirement under this section must comply with the security requirements set forth in §§ 1309.71 through 1309.73 of this part and the recordkeeping and reporting requirements set forth under parts 1310 and 1313 of this chapter.

8. Section 1309.25 is amended by adding a new paragraph (c) to read as follows:

§ 1309.25 Temporary exemption from registration for chemical registration applicants.

* * * * *

(c) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to manufacture or import prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before [DATE 30 DAYS AFTER PUBLICATION OF A FINAL RULE IN THE **Federal Register**]. The exemption will remain in effect for each person who has made such application until DEA has approved or denied the application. This exemption applies only to registration; all other chemical control requirements set forth in this part and parts 1310, 1313, and 1315 of this chapter remain in full force and effect.

Dated: January 11, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E8-774 Filed 1-17-08; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-127127-05]

RIN 1545-BE68

Guidance on Qualified Tuition Programs Under Section 529

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: This document invites comments from the public regarding rules under section 529 of the Internal Revenue Code (Code) that the IRS and the Treasury Department expect to propose in a notice of proposed rulemaking. The rules focus mainly on the transfer tax provisions applicable to accounts (section 529 accounts) in Qualified Tuition Programs (QTPs). It is anticipated that these rules will generally apply to section 529 accounts after the effective date of final regulations. All materials submitted will be available for public inspection and copying.

DATES: Written and electronic comments must be submitted by March 18, 2008.

ADDRESSES: Send written comments to: Internal Revenue Service, Attn: CC:PA:LPD:PR (REG-127127-05), room 5203, POB 7604 Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-127127-05), Courier's Desk, Internal Revenue Service, 1111 Constitution Ave., NW., Washington, DC, or sent electronically, via the Federal eRulemaking Portal at www.regulations.gov (IRS-REG-127127-05).

FOR FURTHER INFORMATION CONTACT:

Concerning submissions, Richard A. Hurst at Richard.A.Hurst@ircounsel.treas.gov or, (202) 622-7180; concerning rules relating to estate, gift, and generation-skipping transfer tax issues, Mary Berman, (202) 622-3090; concerning other proposed rules, Monice Rosenbaum, (202) 622-6070 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Prior Administrative Guidance

A Notice of Proposed Rulemaking under section 529 was published in the **Federal Register** on August 24, 1998 (REG-106177-97; 63 FR 45019) (the 1998 proposed regulations). Additional

guidance was published in Notice 2001-55 (2001-2 CB 299) and Notice 2001-81 (2001-2 CB 617). Notice 2001-55 provides guidance regarding the statutory restriction against investment direction. Notice 2001-81 provides guidance on recordkeeping, reporting and other requirements applicable to QTPs in light of certain amendments made to section 529 by the Economic Growth and Tax Relief Reconciliation Act of 2001 (Pub. L. 107-16, 115 Stat. 38) (EGTRRA). See § 601.601(d)(2)(ii)(b).

Although the 1998 proposed regulations and these notices provide rules regarding many issues arising under section 529, other issues remain unresolved. Current law regarding the transfer tax treatment of section 529 accounts is unclear and in some situations imposes tax in a manner inconsistent with generally applicable transfer tax provisions of the Code. In addition, current law raises the potential for abuse of section 529 accounts in certain situations.

Pension Protection Act of 2006

The Pension Protection Act of 2006 (Pub. L. 109-280, 120 Stat. 780) (the PPA) permanently extended the EGTRRA amendments to section 529, which previously were scheduled to expire at the end of 2010, including the provision that exempts from Federal income tax distributions made from section 529 accounts that are used to pay qualified higher education expenses (QHEEs). See section 1304(a) of the PPA. At the same time, section 1304(b) of the PPA enacted section 529(f). Section 529(f) provides that, notwithstanding any other provision of section 529, the Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of section 529 and to prevent abuse of such purposes, including regulations under chapters 11, 12, and 13.

In discussing new section 529(f), the Technical Explanation prepared by the Joint Committee on Taxation provides two examples of how present law creates the opportunity for abuse of section 529 accounts. See Joint Committee on Taxation, Technical Explanation of H.R. 4, The "Pension Protection Act of 2006," as Passed by the House on July 28, 2006 and as Considered by the Senate on August 3, 2006, (JCX-38-06), at 369. Abuse may arise because of the ability to change designated beneficiaries (DBs) in certain circumstances without triggering transfer tax. For example, taxpayers may seek to establish and contribute to multiple accounts (taking advantage of the 5-year rule of section 529(c)(2)(B))