

Regulatory Analyses

The Department of State is publishing this rulemaking as a final rule, pursuant to 5 U.S.C. 553(b). This rulemaking is a rule of agency organization, procedure, or practice. The effective date of the rule is 30 days after publication, as provided in the Administrative Procedure Act.

The Department further finds that this is not a major rule; is not subject to the Unfunded Mandates Reform Act of 1995; will not have tribal implications as defined by Executive Order 13175; and will not have an impact on a substantial number of small entities under the Regulatory Flexibility Act. This rule is not an economically significant rule under Executive Order 12866, and the Department certifies that the benefits of this rulemaking outweigh any costs, which are minimal for the public. The Office of Information and Regulatory Affairs designated this rule as “non-significant,” as defined by Executive Order 12866.

The Department of State has reviewed this rule in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden. This rule will not have substantial direct effect on the states, on the relationships between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

This rulemaking does not create or modify any collections of information subject to the Paperwork Reduction Act.

List of Subjects in 22 CFR Part 62

Cultural exchange programs, Reporting and recordkeeping requirements.

For the reasons set forth above, the Department of State amends part 62 of title 22 of the Code of Federal Regulations as follows:

PART 62—EXCHANGE VISITOR PROGRAM

■ 1. The authority citation for part 62 is revised to read as follows:

Authority: 8 U.S.C. 1101(a)(15)(J), 1182, 1184, 1258; 22 U.S.C. 1431 *et seq.*; 22 U.S.C. 2451 *et seq.*; 22 U.S.C. 2651a; 22 U.S.C. 6531–6553; Reorganization Plan No. 2 of 1977, 42 FR 62461, 3 CFR, 1977 Comp. p. 200; E.O. 12048, 43 FR 13361, 3 CFR, 1978 Comp., p. 168; 8 U.S.C. 1372; section 416 of Pub. L. 107–56, 115 Stat. 354 (8 U.S.C. 1372 note); and 8 U.S.C. 1761–1762.

■ 2. Section 62.27(e)(1) and (e)(4)(i) are revised to read as follows:

§ 62.27 Alien physicians.

* * * * *

(e) * * *

(1) The duration of an alien physician’s participation in a program of graduate medical education or training as described in paragraph (b) of this section is limited to the time typically required to complete such program. Duration shall be determined by the Secretary of State at the time of the alien physician’s entry into the United States. Such determination shall be based on criteria established in coordination with the Secretary of Health and Human Services and which take into consideration the requirements of the various medical specialty boards as set forth by the Accreditation Council for Graduate Medical Education (ACGME).

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(4) * * *

(i) Alien physicians shall be permitted to undertake graduate medical education or training in a specialty or subspecialty program whose board and/or accreditation requirements are not published if the program requirements are certified to the Secretary of State by the ACGME in accordance with criteria established by the Educational Commission for Foreign Medical Graduates (ECFMG) and ACGME.

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Zachary A. Parker,

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Department of State.*

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POSTAL SERVICE

39 CFR Part 113

Treatment of E-Cigarettes in the Mail

AGENCY: Postal Service™.

ACTION: Guidance.

SUMMARY: A forthcoming final rule will determine whether electronic nicotine delivery systems (“ENDS”) may continue to be mailed pursuant to certain statutory exceptions that are currently administered through an application process. To the extent that such exceptions may ultimately be made available for ENDS, this document provides mailers with guidance to assist in preparing exception applications for submission following the final rule. In addition, ENDS mailers are advised to review and comply with all other

applicable mailing restrictions and requirements currently in effect for controlled substances, drug paraphernalia, and hazardous materials.

DATES: April 19, 2021.

FOR FURTHER INFORMATION CONTACT: Dale E. Kennedy, 202–268–6592.

SUPPLEMENTARY INFORMATION: On February 19, 2021 (86 FR 10218), the Postal Service published a notice of proposed rulemaking to amend Publication 52, *Hazardous, Restricted, and Perishable Mail*, which is incorporated by reference into 39 CFR part 113. The text of the proposed edits to Publication 52 is available at <https://pe.usps.com/FederalRegisterNotice/2021/E-Cigarettes%20Proposed%20Rule.pdf>. The proposed edits would implement the Preventing Online Sales of E-Cigarettes to Children Act (“Act”), Public Law 116–160, div. FF, title VI (2020), which adds “electronic nicotine delivery systems” (“ENDS”) to the definition of “cigarettes” subject to regulation under the Jenkins Act, 15 U.S.C. 375 *et seq.* Consequently, ENDS will also become subject to the mailability restrictions and exceptions in 18 U.S.C. 1716E (“PACT Act”), which rely on the Jenkins Act definition of “cigarettes.” 18 U.S.C. 1716E(a)(1).

Certain such exceptions currently require application to and approval by the Postal Service’s Pricing and Classification Service Center. See Publication 52 sections 472.221 (business/regulatory purposes), 472.241 (consumer testing/public health). The Postal Service proposed to apply the business/regulatory purposes exception to ENDS, but not the consumer testing and public health exceptions, and invited comments on that proposed approach. Those comments will be considered in developing the final rule. The final rule will contain the Postal Service’s determination as to whether any of those exceptions will be made available for nonmailable ENDS.

Until the final rule is issued, ENDS are not subject to the PACT Act, although they may be nonmailable for other reasons. See, e.g., 18 U.S.C. 1716(a), (h) (poisonous, explosive, and other dangerous materials, and advertising, promotional, or sales matter relating to the same); 21 U.S.C. 843(b)–(c), 863 (controlled substances, drug paraphernalia, and advertisements relating to the same); 39 U.S.C. 3018 (hazardous materials); Publication 52 sections 31–349, 453 & appx. A, C. Regardless of the legal status of any products under state or local laws, violations of these Federal mailability laws can result in civil and/or criminal penalties.

The Postal Service has received numerous inquiries and comments about the possibility of submitting exception applications for ENDS products in advance of the final rule. Several commenters express the ENDS industry's concerns about the continuity of supply chains and regulatory compliance activities that rely on the mails, to the extent that such reliance may permissibly continue under the PACT Act. The Postal Service understands that those concerns are heightened by Congress's decision to make ENDS nonmailable immediately upon publication of the final rule, rather than applying the 30-day notice period that typically follows a final rule under the Administrative Procedure Act. Therefore, this document is intended to clarify the state of the exception application process in advance of the final rule and to provide guidance to mailers interested in availing themselves of any exceptions that may ultimately be made available.

Exception Application Process; Preparatory Guidance

The Postal Service cannot accept early applications for PACT Act exceptions relating to ENDS products at this time. The Postal Service has not yet determined whether and to what extent those exceptions will be extended to ENDS. Early acceptance of applications would pose significant administrative challenges for the very Postal Service personnel who are developing the final rule amid substantial public comment under a tight timeframe.

If any of the relevant exceptions are ultimately made available for ENDS, then, given the highly decentralized nature of the ENDS industry relative to the industries historically covered by the PACT Act, the Postal Service anticipates receiving ENDS-related exception applications at a rate several orders of magnitude above the historic norm. Moreover, those applications are expected to involve numbers of parties and products far greater than past PACT Act applications. These factors translate into a load on Postal Service resources that would massively outstrip historically allocated levels. The Postal Service is contemplating reforms to its application process to contend with this manifold near-term increase in complexity that would result from extending the exceptions to ENDS, as well as studying how to improve the process's efficiency and accessibility in the longer term.

Whether any ENDS mailers may ultimately be allowed to use the exceptions remains to be determined. The Postal Service is not in an

administrative position to begin accepting ENDS-related exception applications at this time, and it may not be in such a position until issuance of the final rule. If, contrary to expectation, circumstances permit earlier acceptance of ENDS-related exception applications on a provisional basis, the Postal Service will issue further notice to that effect.

If the final rule does make the business/regulatory purposes and/or consumer testing/public health exceptions available for ENDS and applications are accepted through a reorganized process, applicants should expect review of their applications to require potentially substantial processing time, in light of the statutory requirements for Postal Service verification of mailers' and recipients' eligibility. 18 U.S.C. 1716E(b)(3)(B)(ii)(I)–(II), (b)(5)(C)(ii)(I). The duration of any review would be determined by the number and complexity of the applications that the Postal Service receives and the amount of engagement with applicants during processing.

The following guidance is aimed at facilitating Postal Service review and potentially reducing processing times for any potential exception applications relating to ENDS, should they be permitted under the final rule.

Documentation. With respect to the relevant exceptions, the PACT Act requires the Postal Service to verify mailers' and recipients' eligibility, which includes whether they are "legally operating", "have all applicable State and Federal Government licenses or permits and are engaged in tobacco product manufacturing, distribution, wholesale, export, import, testing, investigation, or research." 18 U.S.C. 1716E(b)(3)(A)(i), (b)(3)(B)(ii)(I)–(II), (b)(5)(A), (b)(5)(C)(ii)(I). Applicants for the consumer testing exception must also be (or be legally authorized agents of) legally operating cigarette manufacturers with "a permit, in good standing, issued under section 5713 of the Internal Revenue Code of 1986." *Id.* at (b)(5)(A)(i).

To the extent that the final rule may make any of these exceptions available for shipments of ENDS, prospective applicants may wish to prepare by compiling electronic copies of all relevant license and permit documentation for themselves and, with respect to the business/regulatory purposes exception, each addressee that they intend to identify in their exception application.

For intended business/regulatory purposes exception applications by organizations engaged in testing,

investigation, or research and those listing such organizations as addressees, relevant documentation may include such materials that would demonstrate the organizations' authorization to engage in the relevant activities (*e.g.*, grant or contract approval documents showing the scope and duration of a relevant research project).

Indexing. Prospective applicants for the business/regulatory purposes exception should prepare a spreadsheet that contains the following data elements with respect to *each sender and recipient address* that they intend to identify in their exception application:

- a. Business or governmental entity name.
- b. Address.
- c. The Postal Service retail or business mail acceptance office(s) where each intended sender would tender shipments.
- d. The Postal Service retail office(s) where each intended recipient would retrieve shipments.
- e. A description of the business or governmental entity (*e.g.*, battery manufacturer, retail store, wholesale distributor, testing laboratory).
- f. For each permit or license, the issuing jurisdiction; the permit or license number; the expiration date (if any); and the activity covered by each current permit or license (*e.g.*, general business operations; sale or manufacture of tobacco products or ENDS).
- g. For each sender or addressee engaged in testing, investigation, or research, the entities authorizing the conduct of such activities; the expiration date (if any) of such authorization; and a brief statement of the subject of each authorization (*e.g.*, health effects of flavor substances, medical effects of cannabidiol ("CBD"), battery safety testing).
- h. The brand name and a description of each product intended to be shipped by each sender or to each addressee.
- i. Whether any identified products or other intended shipments from each sender or to each addressee contain lithium batteries, nicotine, CBD, or tetrahydrocannabinol ("THC").
- j. For products containing nicotine or THC, the intended quantity of the product per shipment and the concentration of nicotine or THC.
- k. For products containing CBD with a THC concentration not exceeding 0.3 percent, whether the CBD derives from hemp.

Mailability Beyond the PACT Act

ENDS implicate mailability statutes and regulations beyond the PACT Act. These statutes and regulations already

render certain substances and components nonmailable, and they will continue to do so with respect to any ENDS shipments that remain mailable pursuant to exceptions or exclusions under the impending final rule. ENDS that become nonmailable under the PACT Act can additionally violate other mailability statutes and regulations. These restrictions and requirements govern the use of the federal mail system, regardless of the legal status of any items under state or local law. Violations of these mailability laws can result in civil or criminal penalties. Therefore, all persons currently or prospectively engaged in the mailing of ENDS—including, in particular, those who intend to continue mailing ENDS under any potentially available PACT Act exceptions—are advised to review Publication 52 carefully. Certain pertinent issues are highlighted below, but this list is not necessarily exhaustive.

CBD products. For hemp-based products containing CBD with a THC concentration not exceeding 0.3 percent, mailers must retain, and prepare to make available upon request, records establishing compliance with all applicable federal, state, and local laws pertaining to hemp production, processing, distribution, and sales, including the Agricultural Act of 2014 and the Agricultural Improvement Act of 2018. Such records may include laboratory test results, licenses, and compliance reports. *See* Publication 52 section 453.37.

Controlled substances and drug paraphernalia. All other substances that contain THC are Schedule I controlled substances for purposes of federal law, 21 CFR 1308.11(d)(31), and are therefore nonmailable in most instances. 21 U.S.C. 843(b); Publication 52 section 453. Products used with such substances may qualify as nonmailable drug paraphernalia. *See* 21 U.S.C. 863; Publication 52 section 453. This federal mailing prohibition is unaffected by whether the mailing of THC-containing substances violates state or local law and by the restriction of Department of Justice appropriations relating to medical marijuana. *See* Public Law 116–260, div. B, title V, section 531 (2020).

Advertisements for controlled substances and drug paraphernalia. It is unlawful to mail advertisements for, or to advertise the mailing of, federally controlled substances or drug paraphernalia. 21 U.S.C. 843(b), (c)(1); *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (“DMM”) section 601.9.4.1.

Hazardous materials: Solutions. Toxic and flammable substances are

nonmailable except subject to requirements designed to render them nonhazardous in the mails and/or in air transportation. 18 U.S.C. 1716(a)–(b); 39 U.S.C. 3018; Publication 52 sections 31–349, 711–728 & appx. A, C. Mailers of ENDS solutions should carefully review the chemical constituents of those products and ascertain the flashpoint of each constituent substance, its toxicological profile, and its concentration in the relevant solution. Nicotine is a toxic substance, for example. In addition, ENDS liquids—including non-nicotine-containing liquids—may contain acetals, acetoin (acetyl methyl carbinol), aldehydes, butanol, diacetyl (butanedione), propanol, and other compounds that qualify as flammable or toxic substances. *Compare* 49 CFR 172.101; Publication 52, appx. A, with Hanno C. Erythropel et al., *Formation of Flavorant-Propylene Glycol Adducts with Novel Toxicological Properties in Chemically Unstable E-Cigarette Liquids*, 21 *Nicotine & Tobacco Research* 1248 (2018); Joseph G. Allen et al., *Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes*, 124 *Enviro. Health Perspectives* 733 (2016).

Depending on a substance’s flashpoint or lethal dose (LD₅₀) and its concentration in a solution, the substance may or may not be prohibited or subject to special Department of Transportation requirements as a hazardous material. *See generally* Publication 52 sections 343, 346 & appx. A, C. Such items may be prohibited from or restricted in air transportation and may not be eligible for shipping via Priority Mail Express, Priority Mail, First-Class Mail, or First-Class Package Service. *Id.* sections 327, 711–728. Even nonregulated toxic liquids and solids may be subject to quantity restrictions, packaging requirements, and restrictions on the availability of Postal Service shipping options. *See* Publication 52 sections 346.232.

Hazardous materials: Lithium batteries. Mailers of lithium metal or lithium-ion batteries should be aware of applicable restrictions and requirements, which may determine mailability, packaging, product design, shipping quantities, and the availability of relevant Postal Service products. *See* Publication 52 section 349.221–.222, 711–728.

Non-hazardous liquids. Mailers of liquids that are not regulated as hazardous materials (whether or not such liquids contain nicotine) should be aware of applicable packaging

requirements. *See* Publication 52 section 451.3 and DMM section 601.3.4.

Hazardous and restricted materials: Advertising, promotional, or sales matter. To the extent that ENDS may be subject to special requirements as hazardous or otherwise restricted materials, then matter that solicits or induces the mailing of such items is mailable only if it contains all pertinent packaging instructions and any other mailing limitations. 18 U.S.C. 1716(h); DMM section 601.9.4.1.

Conclusion

Again, it is emphasized that the Postal Service has yet to determine whether and to what extent any PACT Act exceptions may be made available for ENDS. Nevertheless, mailers of ENDS products may find the preparatory information above useful in preparing for the potential availability of such exceptions following a final rule. In addition, all persons currently or prospectively engaged in the mailing of ENDS products should carefully review non-PACT-Act-related mailing prohibitions, restrictions, and other requirements that may apply to ENDS products, to ensure that their use of the mail system is safe and compliant with Federal law.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0189; FRL–10022–74–Region 6]

Air Plan Approval; Arkansas; Arkansas Regional Haze and Visibility Transport State Implementation Plan Revisions; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a final rule that appeared in the **Federal Register** on March 22, 2021, and that will become effective on April 21, 2021. The EPA finalized approval of a revision to the Arkansas State Implementation Plan (SIP) submitted by the State of Arkansas through the Arkansas Department of Energy and Environment, Division of Environmental Quality (DEQ). This document corrects an error in the regulatory text. This correction does not