samidorphan. Samidorphan is not currently available or marketed in any country. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates, if any, of samidorphan, DEA is unable to determine the number of entities and small entities which might handle samidorphan. In some instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, DEA is able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, DEA does not have a basis to estimate whether samidorphan is expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, DEA is unable to estimate the number of entities and small entities who plan to handle samidorphan.

Although DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this final rule, a qualitative analysis indicates that this rule is likely to result in some cost savings. Any person planning to handle samidorphan will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements. Because of these factors, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

Administrative Procedure Act

DEA finds that good cause exists for adopting this rule as a final rule with an immediate effective date under 5 U.S.C. 553(d) because this final rule relieves a restriction.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the RFA section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* that this action would not result in any federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year. . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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 (CRA)). This rule will not result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; 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. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b) unless otherwise noted.

■ 2. In § 1308.12, revise paragraph (b)(1) introductory text to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following:

* * * * *

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–07884 Filed 4–16–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 62

[Public Notice: 10818]

RIN 1400–AF03

Change to Certification Authority for the Alien Physician Category of the Exchange Visitor Program

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (Department) is changing the certification authority for alien physicians from the American Board of Medical Specialties (ABMS) to the Accreditation Council for Graduate Medical Education (ACGME).

DATES: This rule is effective May 19, 2021.

FOR FURTHER INFORMATION CONTACT: G. Kevin Saba, Director, Office of Policy and Program Support, Office of Private Sector Exchange, Bureau of Educational and Cultural Affairs, U.S. Department of State, SA–4E, 2201 C Street NW, Washington, DC 20522; email at *JExchanges@state.gov*; or, (202) 634–4710.

SUPPLEMENTARY INFORMATION: In 22 CFR 62.27(e)(1) and (e)(4)(i), there is a reference to the ''American Board of Medical Specialties'' (ABMS). These provisions, last amended in 1993, state that ABMS will perform certain certification functions for the Secretary of State.

ABMS no longer produces the publication, *Marquis Who's Who,* referenced in 22 CFR part 62. Furthermore, ABMS has confirmed that it is also no longer the appropriate organization to comment on programs of graduate medical education. The Department has confirmed that the Accreditation Council for Graduate Medical Education (ACGME) has responsibility to accredit and recognize institutions offering programs of graduate medical education, and is replacing the reference to the ABMS with the ACGME in § 62.27.

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).

* * * * *

(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.

* * * * *

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2021–07537 Filed 4–16–21; 8:45 am]

BILLING CODE 4710–05–P

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.